FORM PTO-1390 (REV. 12-2001) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: CARDE.59410

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/031826

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/01485	22 January 2000	22 January 1999

TITLE OF INVENTION: Aortic Catheter with Flow Divider and Methods for Preventing Cerebral Embolization

APPLICANT(S) FOR DO/EO/US: John A. MACOVIAK

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [x] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [x] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [ ] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [x] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [ ] has been communicated by the International Bureau.
   c. [x] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [ ] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [x] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [ ] Other items or information:

10/031826 - 102802

531 Rec'd PCT/ 18 JAN 2002

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/031826	PCT/US00/01485	CARDE.59410

21. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 100.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130.00	

CLAIMS	NUMBER FILED		NUMBER EXTRA	RATE		
Total claims	50	- 20 =	30	x **$18.00**	$ 540.00	
Independent claims	2	- 3 =	0	x **$84.00**	$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ **$280.00**	$ 0.00	
TOTAL OF ABOVE CALCULATIONS =					$ 770.00	
☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				+	$ 385.00	
SUBTOTAL =					$	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					$	
TOTAL NATIONAL FEE =					$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +					$	
TOTAL FEES ENCLOSED =					$ 385.00	
					Amount to be refunded:	$
					charged:	$

a. ☒ A check in the amount of $ 1025 to cover the above fees is enclosed. Includes $640 for small entity Petition to Revive

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

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AORTIC CATHETER WITH FLOW DIVIDER AND METHODS FOR PREVENTING CEREBRAL EMBOLIZATION

FIELD OF THE INVENTION

This invention relates to a catheter system that reduces the volume of embolic material, which may be knocked loose from an artery wall or the wall of a chamber of the heart as a result of a medical procedure, from entering a selected oxygenated blood carrying artery system. More specifically, the invention relates to a catheter for isolating and perfusing a segment of a patient's cardiovascular system and for directing circulatory flow around the isolated segment. More particularly, it relates to an apparatus for deployment within a patient's aortic arch and to methods for selectively perfusing the arch vessels with a fluid, while directing blood flow within the aortic lumen past the isolated arch vessels.

BACKGROUND OF THE INVENTION

In the field of cardiovascular surgery, it has been common practice for surgeons to perform a sternotomy to expose the body cavity in the thorax region, wherein retractors are employed to provide the necessary access to internal structures to perform the medical procedures. Depending on the medical procedure to be performed, it has often been necessary to arrest heart activity for some period of time during the procedure. The blood is then diverted through a cardiopulmonary bypass pump in order to maintain sufficient oxygenated blood flow to the body. Procedures performed as described above cause significant trauma to the body due to the method of entry into the thorax region, and the cessation of heart activity. Recent trends in the development of surgical devices have been toward the use of less invasive techniques, so that operations cause less extensive trauma. Furthermore, there has been a trend toward reducing the amount of time the heart is stopped, or eliminating the step of stopping the heart altogether.

One major disadvantage to any procedure performed on the heart or on major arteries associated with the heart, even for less invasive procedures, is that embolic material may be knocked loose from arterial walls, heart valves, or from the interior walls of the chambers of the heart, and pumped to the brain, where the resulting blockages may cause neurologic damage.

Cardiopulmonary bypass pumps are frequently used to pump blood in the patient while the heart is stopped during surgery, and bypass pumps generally include a filter mechanism to trap embolic material from the blood before the oxygenated blood is returned to the body. However, when the heart is started, embolic material from within the heart may be pumped to the brain. Aortic perfusion shunts, as described in commonly owned and copending U.S. patent application, serial number 09/212,580, filed December 15, 1998, claiming the benefit of provisional application, serial number 60/069,470, filed December 15, 1997, hereby incorporated in its entirety, have been developed that allow the blood from the heart to perfuse the body, while providing separate perfusion of the arch vessels. The aortic perfusion shunts described represent a significant step forward in protection against cerebral embolization, however, there remains a tremendous need for further improvements in devices and methods for protecting a patient against the potential of cerebral embolization.

What is needed is a catheter device for use in minimally invasive medical procedures and for standard open chest surgery that is simple and relatively inexpensive and that is capable of isolating the circulation of the arch vessels, while still allowing the heart to perform the function of perfusing the body of the patient.

SUMMARY OF THE INVENTION

Accordingly, the invention is a catheter with a fluid flow control member called a deflector or a fluid flow divider positioned near the distal end of the catheter for dividing a first lumen into two channels near a point where a second lumen branches from the first lumen, and for perfusing the branch lumen. The invention will be described more specifically herein relating to an aortic catheter having a divider positioned in the aortic arch proximate the arch vessels.

The flow divider may be formed in a variety of configurations. In general, the flow divider will have an undeployed or collapsed state and an expanded or deployed state. The flow divider may be deployed from an exterior surface of the catheter shaft, or it may be deployed from within a lumen in the catheter shaft. In embodiments wherein the flow divider is coupled to an exterior surface, the flow divider will preferably have an undeployed state wherein the flow divider is contained in a relatively small volume around the circumference of the distal end (nearest the heart) of the catheter, having an exterior circumference that is preferably not significantly larger than the exterior circumference of the catheter. In embodiments wherein the flow divider is deployed from within the catheter, the flow divider

preferably has an undeployed state that is sized and configured for storage within a lumen in the catheter. In both configurations, the catheter will generally have a deployed state in which the length and width of the flow divider is sufficient to divide blood flow in the aorta in the vicinity of the ostia of the arch vessels.

The flow divider may comprise one or more inflatable chambers or one or more selectively deployable shrouds. The inflatable chambers may be relatively non-compliant or they may be compliant, exhibiting elastic behavior after initial inflation to closely fit the aortic lumen size and curvature.

The catheter may further include one or more additional or auxiliary flow control members located upstream or downstream from the flow divider to further segment the patient's circulatory system for selective perfusion to different organ systems within the body or to assist in anchoring the catheter in a desired position. These auxiliary flow control members may comprise inflatable balloons or selectively deployable external catheter valves. The anchoring members may be inflatable balloons or other anchoring structures that provide sufficient force or friction to prevent the catheter from drifting from a selected position within the aorta. The catheter may also include a selectively deployable embolic filter for capturing embolic materials in the aortic blood flow.

In a preferred embodiment, the catheter shaft includes at least three lumens, one lumen for inflating or otherwise deploying the flow divider, a second for perfusion of the arch vessels, and a third guidewire lumen. In alternate embodiments, additional lumens may be included for deploying the auxiliary flow control members, for measuring the pressure at desired locations within the aorta, and for perfusion of the patient's corporeal circulation. The catheter may be configured for retrograde deployment via a peripheral artery, such as the femoral artery, or it may be configured for antegrade deployment via an aortotomy incision or direct puncture in the ascending aorta.

Methods according to the present invention are described using the aortic catheter for occluding and compartmentalizing or partitioning the patient's aortic lumen, for performing selective filtered aortic perfusion and for differential perfusion of the patient's circulatory system.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG 1 shows a bottom view of a first embodiment of the aortic catheter of the invention configured for retrograde deployment via a peripheral artery access point, such as the femoral artery.

FIG 2 shows a side view of the catheter of FIG 1, showing the flow divider in a collapsed state.

FIG 3 shows a cross section of the aortic catheter of FIG 1 taken along line 3-3 in FIG 1.

FIG 4 shows a top view of the catheter of FIG 1 with the flow divider deployed.

FIG 5 shows a perspective view of the distal region of the catheter of FIG 1 deployed within an aortic arch.

FIG 6 shows a side view of the catheter of FIG 5 deployed within an aortic arch.

FIG 7 shows a lateral cross section of the aortic lumen and of the catheter of FIG 6 taken along line 7-7.

FIG 8 shows an alternate embodiment of the catheter of FIG 7, with the flow divider curved in a direction opposite that shown in FIG 7.

FIG 9 shows an embodiment of the catheter of the invention wherein a distal end of the catheter extends through the divider and beyond the end of the divider.

FIG 10 shows an embodiment of the catheter of the invention wherein the catheter shaft extends below the divider, then above the divider, and then below the divider again, at different points along the catheter.

FIG 11 shows a side view of the catheter of FIG 10 deployed within the aortic arch.

FIG 12 shows a catheter similar to the catheter of FIG 10, but with the divider periphery concave on its upper surface.

FIG 13 shows a perspective view of an embodiment of the catheter of the invention including a deployed auxiliary flow control member positioned between the flow divider and the distal end of the catheter.

FIG 14 shows a perspective view of the catheter of FIG 13 with the auxiliary flow control member partially collapsed.

FIG 15 shows an embodiment of the catheter of the invention configured for antegrade deployment.

FIG 16 shows another embodiment of the catheter of the invention configured for antegrade deployment, showing a divider that is significantly shorter than the divider described in previous embodiments.

FIG 17 shows a cut-away view of an embodiment of the flow divider including a mesh or porous portion for perfusing from the upper surface of the flow divider.

FIG 18 shows a cut-away view of an alternate internal structure of the flow divider of FIG 17.

FIG 19 shows an embodiment of the flow divider of the invention comprising a peripheral tube and membrane structure.

FIG 20 shows a cross section of the flow divider of FIG 19 taken along line 20-20.

FIG 21 shows an embodiment of the flow divider of the invention with welds or joined areas between an upper and a lower film of the flow divider to give additional structure and rigidity to the flow divider.

FIG 22 shows a cross section of the flow divider of FIG 20 taken along line 22-22.

FIG 23 shows an alternate embodiment of FIG 21 with larger joined areas between the upper and lower films of the flow divider.

FIG 24 shows an embodiment of the flow divider having a membrane or film portion and a peripheral tube portion, that is deployed using a pair of wires.

FIG 25 shows a cross section of the flow divider of FIG 24 taken along line 25-25.

FIG 26 shows a cross section of an embodiment of the flow divider that is sack-like, rather than having a peripheral channel, and that uses a pair of deployment wires to deploy.

FIG 27 shows an alternate embodiment of the flow divider of FIG 24 that is deployed using only a single wire.

FIG 28 shows a perspective view of an embodiment of the catheter of the invention wherein the flow divider comprises a shroud deployed by means of movable ribs.

FIG 29 shows a top view of the catheter of FIG 28 in a collapsed configuration.

FIG 30 shows a top view of the catheter of FIG 28 in a deployed configuration.

FIG 31 shows an embodiment of the flow divider of the invention deployed from a lumen within a catheter.

FIG 32 shows a cross section of the flow divider and aorta of FIG 31 taken transversely through the aorta.

FIG 33 shows a flow divider, having a flexible stiffening spine, deployed from within a lumen having an opening in the distal end of the catheter and coupled to a deployment wire at a point intermediate the ends of the spine.

FIG 34 shows the flow divider and catheter of FIG 33 with the deployment wire retracted to the distal end of the catheter so that the catheter is positioned for perfusion of the arch vessels.

FIG 35 shows the flow divider of FIG 33 partially withdrawn into the catheter.

FIG 36 shows an alternate embodiment of the flow divider of FIG 33 with an additional withdrawal wire.

FIG 37 shows the flow divider of FIG 36 partially withdrawn into the catheter.

FIG 38 shows a fully deployed flow divider similar in construction to the flow divider of FIG 28, but that is deployed from within a lumen in a catheter shaft.

FIG 39 shows the flow divider of FIG 38 in an undeployed state within the catheter.

FIG 40 shows the flow divider of FIG 38 partially deployed.

FIG 41 shows an embodiment of the flow divider comprising a flexible tongue that is folded back within the catheter shaft, and deployed using a deployment wire to push the flow divider out.

FIG 42 shows the flow divider of FIG 41 fully deployed, and with the deployment wire retracted.

FIGS 43A-F show an aortic catheter with a flow divider configured for differential perfusion of a patient's circulatory system.

FIGS 44A-C show a side perspective view of a distal end portion of the aortic catheter of FIG 43A.

FIGS 45A-B show a top and bottom view of the distal end portion of the aortic catheter of FIG 43A.

FIG 46 shows a top view of an alternate construction for the flow divider of FIG 43A.

FIGS 47A-B show a flow divider configured with a lower support member for supporting the flow divider within the aortic arch.

FIGS 48A-B show the flow divider of FIG 47A deployed within a patient's aortic arch.

FIG 49 shows an aortic catheter with a flow divider configured for femoral artery introduction and having a pigtail distal end on the catheter for supporting the flow divider within a patient's aortic arch.

FIG 50 shows an aortic catheter with a flow divider configured for femoral artery introduction and having an extendable lower support member for supporting the flow divider within a patient's aortic arch.

FIG 51 shows a flow divider with an auxiliary flow control member positioned at an upstream end of the flow divider.

FIG 52 shows a flow divider with an auxiliary flow control member positioned near the center of the flow divider.

FIG 53 shows a flow divider with an aortic filter for capturing embolic material.

FIG 54 shows a flow divider with an arch perfusion filter deployed within a patient's aortic arch.

FIG 55 shows a distal end view the flow divider of FIG 54.

FIG 56 shows a flow divider with fiberoptic illumination.

FIG 57 shows a flow divider with an internal support wire being inserted into a patient's aortic arch.

FIG 58 shows the flow divider of FIG 57 deployed within the patient's aortic arch.

FIG 59 shows a flow divider with an internal support wire configured for differential perfusion of a patient's circulatory system.

FIG 60 shows the flow divider of FIG 59 with the additional feature of an auxiliary flow control member.

FIG 61 shows the flow divider of FIG 59 with the additional feature of a selectively deployable aortic filter.

DETAILED DESCRIPTION OF THE INVENTION

The catheter described herein with all of its preferred features represents a versatile device having multiple uses. The invention provides a catheter having a flow divider positioned near the distal end of the catheter for dividing the blood flow through a lumen, preferably at a point where at least one second lumen branches from the first lumen, and for perfusing the branch lumen or lumens. However, the invention will be described more specifically herein relating to an aortic catheter having a flow divider configured to be positioned in the aortic arch and having a length sufficient to divide the blood flow in the aortic lumen so that the arch vessels are at least partially isolated.

The flow divider may be formed in a variety of configurations. In general the flow divider will have an undeployed state wherein the flow divider is contained in a relatively small volume around the circumference of the distal end of the catheter, nearest the heart. The catheter will generally have a deployed state in which the length and width of the flow divider is sufficient to divide blood flow in the aorta in the vicinity of the ostia of the arch vessels, and an undeployed state in which the flow divider is collapsed around the shaft of the catheter and preferably has an exterior circumference that is not significantly larger than the exterior circumference of the catheter.

The flow divider may comprise one or more inflatable chambers or one or more selectively deployable shrouds. The inflatable chambers may be relatively non-compliant or they may be compliant, exhibiting elastic behavior after initial inflation, for example, to closely fit the aortic lumen size and curvature.

The catheter may further include one or more additional or auxiliary flow control members located on the catheter either distal or proximal from the flow divider to further segment the patient's circulatory system for selective perfusion to different organ systems within the body or to assist in anchoring the catheter in a desired position. These auxiliary flow control members may comprise inflatable balloons or selectively deployable external catheter valves. The anchoring members may be inflatable balloons or other anchoring structures that provide sufficient force or friction to prevent the catheter from drifting from a selected position within the aorta.

Usable auxiliary flow control members include, but are not limited to, expandable or inflatable members such as inflatable balloons and valves including collapsible/expandable valves of various configurations including retrograde valves, antegrade valves, and various central flow and peripheral flow valves. A combination of valves and inflatable members may be used as appropriate for a given procedure, thus in some embodiments, the catheter body can include one or more antegrade and retrograde valves, as well as one or more inflatable balloons. Inflatable balloons and collapsible/deployable valves have been previously described, and are known in the industry, and any desirable or practical inflatable balloon or deployable valve may be used. Inflatable balloons typically include an interior chamber that is in fluid communication with an inflation lumen extending within the catheter shaft from a location from within the respective flow control member to a location in the proximal portion which is adapted to extend out of the patient.

Preferably, the flow divider, and any auxiliary flow control members, or anchoring members, if present, are mounted directly on an elongated catheter shaft. In a preferred embodiment, the catheter shaft includes at least three lumens, one lumen for inflating or otherwise deploying the flow divider, a second for perfusion of the arch vessels, and a third guidewire lumen. In alternate embodiments, additional lumens may be included for deploying the auxiliary flow control members, for measuring the pressure at desired locations within the aorta, or for perfusing other isolated segments of the patient's circulatory system. The catheter may be configured for retrograde deployment via a peripheral artery, such as the femoral artery, or it may be configured for antegrade deployment via an aortotomy incision or direct puncture in the ascending aorta. The catheter is characterized by a flexible catheter shaft

placed by surgical cutdown or needle/introducer guidewire technique into the vessels of the lower or upper extremity or neck. Other large internal vessels may also be used.

Anticoagulants, such as heparin and heparinoids, may be applied to the surfaces of the catheter and/or flow control members as desired. Anticoagulants may be painted or sprayed onto the device. Anticoagulants other than heparinoids may also be used, for example monoclonal antibodies such as REOPRO (Eli Lilly and Co., Indianapolis, IN). A chemical dip comprising the anticoagulant may also be used. Other methods known in the art for applying chemicals to catheters may be used.

Attention is now drawn to the figures, which illustrate examples of several embodiments of the invention, and wherein like numbers refer to similar elements or features. FIG 1 illustrates a first embodiment of the aortic catheter 100 of the invention. The aortic catheter 100 has an elongated catheter shaft 102 having a proximal end 104, that preferably extends out of the patient's body, and a distal end 106 closest to the patient's heart. The elongated catheter shaft 102 preferably has an overall length sufficient to reach from the arterial access point where it is inserted into the patient to its deployed position within the aorta. For femoral artery deployment in adult human patients, the elongated catheter shaft 102 preferably has an overall length from approximately 60 cm to 120 cm, and more preferably 70 cm to 90 cm.

In a preferred embodiment, the elongated catheter shaft 102 has an outer diameter that is preferably approximately 9 to 22 French (3.0 to 7.3 mm), and more preferably 12 to 18 French (4.0 to 6.0 mm) for use in adult human patients. Catheters for pediatric use, or use in non-human subjects, may require different dimensions and would be scaled accordingly. The elongated catheter shaft 102 is preferably formed of a flexible thermoplastic material, a thermoplastic elastomer, or a thermoset elastomer. Suitable materials for use in the elongated catheter shaft 102 include, but are not limited to, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers thereof, as well as braided, coiled or counterwound wire or filament reinforced composites. Additionally or alternatively, the elongated catheter shaft 102 may be constructed using metallic tubing or a solid wire, for example stainless steel hypodermic tubing or wire or superelastic nickel-titanium alloy tubing or wire.

Preferably, the aortic catheter 100 includes one or more location markers 116, such as radiopaque markers and/or sonoreflective markers, to enhance imaging of the aortic catheter 100 during deployment using standard fluoroscopy, ultrasound, MRI, MRA, transesophageal

echocardiography, or other techniques. For example, in the illustrative embodiment shown in FIG 1, a radiopaque location marker 116 is positioned near the distal end 106 of the catheter shaft 102, and another near the proximal end of the flow divider 110, to assist in positioning the flow divider 110 within the aortic arch. The radiopaque location markers 116 may be formed as a ring or disk of dense radiopaque metal such as gold, platinum, tantalum, tungsten, or compounds or alloys thereof, or a ring of a polymer or adhesive material heavily loaded with a radiopaque filler material.

The flow divider 110, of FIG 1, is mounted proximate the distal end 106 of the elongated catheter shaft 102. In the embodiment shown in FIGS 1 through 4, the flow divider 110 is shown in the form of a flat elongate expandable inflatable balloon bonded to the catheter shaft 102 by heat welding or with an adhesive. The inflatable flow divider 110 has a deflated state in which the flow divider 110 adheres closely to the catheter shaft 102 so that the collapsed diameter of the flow divider 110 is, preferably, not substantially larger than the diameter of the catheter shaft 102, and an inflated state in which the flow divider 110 expands to dimensions sufficient to divide blood flow in the aortic arch of the patient into two fluid flow channels. Preferably, the flow divider 110 will be formed so that, when inflated, the flow divider 110 automatically assumes and maintains a desired shape, without any additional stiffening structure. However, in some embodiments, it may be desirable to include means for assisting the flow divider 110 in maintaining a desired shape, and any known means for accomplishing this may be used. For example, the divider may include ribs, support wires or other stiffening structures coupled to the flow divider 110, or formed as an integral part of the flow divider 110. Alternatively, the flow divider 110 may include mattress type welds, or internal welds or columns. The outer surface of flow divider 110 may include a friction increasing means such as a friction increasing coating or texture to increase friction between the flow divider 110 and the aortic wall, when deployed, to assist in maintaining the flow divider 110 in a desired position within the aorta.

FIG 2 is a side view of the catheter 100, showing that the flow divider 110 is preferably coupled only to a portion of the diameter of the catheter shaft 102. Thus, perfusion ports 118 are unobstructed.

FIG 3 is a cross section of the catheter shaft 102 taken along line 3-3. The elongated catheter shaft 102 preferably has at least three lumens, an inflation lumen 108 that is used to deploy the flow divider 110, a perfusion lumen 112 that is used to perfuse one of the fluid flow channels, and a guidewire lumen 114. The configuration of the lumens is shown for

illustrative purposes only, and any reasonable configuration of lumens within the catheter may be used.

The flow divider 110 is shown in a deployed state in FIG 4. Preferably, the flow divider 110 in its deployed configuration includes a distal portion 120 that extends beyond the distal end of the catheter 100 in order to seal snugly against the aortic lumen wall. The proximal portion 122 of the divider 110 is shown shaped similarly to the distal portion 120, however, in this embodiment the shape of the proximal portion 122 of the divider 110 is not critical to the invention and could be triangular, square, or any other desired shape. In other embodiments, it may be preferable that the shape be chosen to encourage low turbulence, or possibly laminar, fluid flow where the fluid flow from the flow channel above the divider 110 and the fluid flow from below the flow divider 110 meet at the trailing edge of the proximal portion 122.

Referring to FIG 5, an aortic catheter 100 of the invention is shown in a cutaway perspective view deployed within a patient's aorta B via femoral artery access. In order to facilitate placement of the catheter 100 within the aorta B, and to improve the stability of the catheter 100 in the proper position in the patient's aorta B, a distal region 124 of the aortic catheter 100 may be preshaped to conform to the internal curvature of the patient's aortic arch. The distal region 124 represents a J-shaped curve of approximately 180 degrees of arc with a radius of curvature of approximately 4 to 10 centimeters, for use in a typical adult human patient. The distal end 106 of the aortic catheter 100 may be skewed slightly out of the plane to accommodate the forward angulation of the typical patient's aortic arch and ascending aorta.

In use, the flow divider 110 is positioned within the aortic arch, as seen in a side view in FIG 6, with the flow divider 110 positioned to redirect blood flow originating from the heart A through a selected region of the aortic lumen B below the divider 110. The edge of the distal end 120 of the flow divider 110, as well as the sides of the flow divider 110, contact the aortic wall. Thus, the aortic lumen B is divided into two channels, one above the aortic divider 110 and one below the aortic divider 110. Blood flow originating from the heart A is prevented from entering the region of the aortic lumen providing blood flow to the arch vessels by the flow divider 110, which directs the blood to the flow channel below the flow divider 110. Blood flow below the flow divider 110 bypasses the arch vessels carrying any embolic material C harmlessly past the cerebral circulatory system. The channel above the flow divider 110 is perfused with a selected fluid, such as oxygenated normothermic blood, oxygenated hypothermic blood, blood substitutes such as PERFLUBRON or other

perfluorocarbon compounds, radiopaque dyes for angiography, or the like, introduced through the perfusion lumen 112 of the catheter shaft 102. The selected fluid exits the catheter shaft 102 through perfusion ports 118. Because the proximal end 122 of the flow divider 110 is not sealed against a wall of the aortic lumen B, it is preferable that the pressure and flow rate of fluid perfused through the catheter 100 be sufficient to prevent back flow from the proximal end 122 of the divider 110 and also to hinder fluid flow around the edges of the flow divider 110. Thus, preferably, only the perfused fluid from the perfusion lumen 112 enters the arch vessels.

In the embodiment shown in FIGS 1 through 7, it is contemplated that some of the selected fluid perfused through the perfusion ports 118 will flow to the arch vessels, and some will flow along the upper surface of the flow divider 110 until the perfused fluid leaves the trailing edge of the flow divider 110. It may be preferable that the blood flow at this point be laminar with little mixing between the fluid originating from the flow channels. However, even if turbulence results near the trailing edge of the flow divider 110, embolic material C in the blood originating from the heart A will have already passed the arch vessels, thereby achieving the objective of preventing embolic material from entering the cerebral circulatory system.

It is not essential that the edges of the flow divider 110 create a perfect seal with the wall of the aorta. Some leakage of blood around the flow divider 110 may be tolerated because the fluid perfused through the perfusion lumen 112 creates a pressure gradient from above the flow divider 110 to below the flow divider 110 so that any potential embolic material will not enter the flow channel above the flow divider 110.

The ability to create a good seal between the aortic lumen and the edges of the flow divider 110 may be enhanced by pre-shaping the flow divider 110 to conform to the aortic lumen. The flow divider 110 may be arcuate along the longitudinal axis of the flow divider 110 as is seen in FIG 7, which shows a cross sectional view of the flow divider 110 taken along lines 7-7 in FIG 6. The curve of the flow divider 110 may help prevent the flow divider 110 from collapsing against the aortic lumen wall when the upper side of the divider 110 is under greater pressure than the lower side of the flow divider 110. As shown in FIG 8, in alternate embodiments, the arch of the flow divider 110 could be reversed.

In an alternate embodiment seen in FIG 9, the distal end 106 of the catheter 100 passes through the flow divider 110 at a point 126 to extend on the opposite side of the flow divider 110. This configuration is useful for procedures wherein it is desired to perfuse the flow

channel below the divider 110 with a selected fluid. The catheter 100 may use an additional separate corporeal perfusion lumen, or alternatively, the guidewire lumen 114 may be used. This embodiment is also usable for configurations including an auxiliary flow control member on the catheter positioned between the distal end 106 of the catheter 100 and the proximal end 122 of the flow divider 110.

FIG 10 discloses a catheter configuration wherein the catheter 116 passes from the lower side of the flow divider 110 at 128 to the upper side of the flow divider 110, and then, from the upper side of the flow divider 110 to the lower side of the flow divider at 126. The flow divider 110 is preferably arcuate, but in an orientation opposite that of the prior embodiments, as seen in the cut-away view of FIG 8. Although, in alternate embodiments, the arch of the flow divider 110 could be reversed, as shown in FIG 7. The catheter of this embodiment is seen in use in an aortic arch in FIG 11. The advantage of this configuration is that both ends 120, 122 of the flow divider 110 seal against the aortic lumen wall, instead of the proximal end 122 of the flow divider 110 being open as in the previous embodiments. Furthermore, in this embodiment it may be preferable to maintain a higher pressure on the lower side of the flow divider 110 than on the upper side of the flow divider 110, for example by perfusing oxygenated blood through the guidewire lumen 114 or an additional separate corporeal perfusion lumen. If the pressure on the lower side of the flow divider 110 is maintained at a higher pressure than the pressure on the upper side of the flow divider 110, the flow divider 110 may be urged upward, causing the edges of the flow divider 110 to contact the aortic wall with greater force, assisting to seal the edges of the flow divider 110 against leakage. FIG 12 shows a flow divider 110 similar to the flow divider 110 of FIG 10, but with the flow divider 110 periphery concave upward, which may assist in sealing the edges of the flow divider 110 against leakage. However, a complete seal is not critical in these or any other embodiments of the invention described herein, as pressure gradients and/or balanced perfusion flow minimizes flow around the edges of the flow divider 110.

Any embodiments of the catheter 100 of the invention described above may further include auxiliary flow control members. The auxiliary flow control members may be used to further compartmentalize the patient's circulatory system, or may be used for other functions such as assisting in securely anchoring the catheter in a chosen position. An example of a catheter of the invention further comprising an auxiliary flow control member is seen in FIG 13, which shows an auxiliary flow control member 130 coupled to the distal end of the

catheter 100 proximate the distal end 120 of the flow divider 110. The auxiliary flow control member 130 is positioned within the aorta and is fully deployed, occluding the aorta. The auxiliary flow control member 130 shown in FIG 13 is an inflatable balloon bonded to the catheter shaft 102 by heat welding or with an adhesive. Alternatively, the auxiliary flow control member 130 could be a deployable valve, or other structure. Deployable valves suitable for use in this application are described in commonly owned U.S. patents 5,827,237 and 5,833,671, which are hereby incorporated in their entirety. Suitable materials for the auxiliary flow control member 130 include, but are not limited to, elastomers, thermoplastic elastomers, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers and reinforced composites thereof. In alternate embodiments, the auxiliary flow control member 130 may be positioned on the proximal side of the flow divider 110, if desired. The auxiliary flow control member 130 may also be used to anchor the catheter 100 so that it does not migrate out of its optimal position during the medical procedure. The outer surface of an auxiliary flow control member 130 used to anchor the catheter 100 may include a friction increasing means such as a friction increasing coating or texture to increase friction between the auxiliary flow control member 130 and the aortic wall, when deployed. Alternatively, an auxiliary flow control member 130, which may be an inflatable balloon or deployable valve, can be mounted on a separate catheter and introduced through a lumen within the catheter 100.

FIG 14 shows the catheter of FIG 13 deployed within an aorta with the flow divider 110 fully deployed, and auxiliary flow control member 130 partially collapsed. As blood flow resumes from the heart A, embolic material C is diverted away from the arch vessels by the flow divider 110.

The previous embodiments have been described using a catheter configured for a retrograde approach to the aorta from a peripheral vessel such as the femoral artery. The invention could easily be modified for alternate deployment means. For example, FIG 15 shows a catheter 100 configured for central antegrade deployment in the aortic arch through an aortotomy or direct puncture in the ascending aorta. The catheter 100 and flow divider 110 is configured similarly to the catheters disclosed in previous embodiments. Other embodiments of the invention may be configured for peripheral insertion through the subclavian or axillary arteries.

FIG 16 shows an alternate embodiment having a very short flow divider 110. In this embodiment, the flow divider 110 does not extend beyond the ostia of the arch vessels, and relies on the creation of two adjacent fluid flow streams or channels that preferably exhibit laminar flow, or low turbulence flow between the two flow streams. Even if some turbulence results near the trailing edge of the flow divider 110, embolic material C in the blood originating from the heart A will preferably have passed the arch vessels before the fluid streams mix significantly. Preferably, the arch vessels receive fluid only from the flow stream originating from the perfusion ports 118 above the flow divider 110.

FIG 17 discloses an alternate embodiment of the flow divider 110, wherein the top surface of the flow divider 110 comprises a mesh or porous region 132. The perfusion ports 118 allow a selected fluid to enter the interior chamber 134 of the flow divider 110 before the fluid passes through the mesh or porous region 132 to perfuse the aorta. The material or materials used in the flow divider 110 are preferably characterized by properties that allow an internal pressure within the flow divider 110 to be maintained at a sufficient level to maintain the deployed configuration of the flow divider 110 to divide the aorta, while also allowing a controlled volume of fluid to escape from the flow divider 110 through the mesh or porous region 132 on the upper surface of the flow divider 110 for perfusing the arch vessels. Thus, the surface of the flow divider 110 may have porous regions that allow a fluid to be perfused at a known rate when a specific pressure is attained. In the embodiment shown in FIG 17, an inflatable peripheral tube 136 surrounds the periphery of the flow divider 110, however, in alternate embodiments, this feature may be omitted. In embodiments including an inflatable peripheral tube 136, it is preferable that the peripheral tube 136 be inflated from a separate additional lumen. However, FIG 18 discloses an embodiment of the flow divider 110 of FIG 17 wherein a single inflation and perfusion lumen may be used. In this embodiment, perfused fluid passes from the catheter 100 into the peripheral tube 136 to inflate the peripheral tube 136. Apertures 138 between the inflatable peripheral tube 136 and the interior chamber 134 of the flow divider 110 allow fluid to flow from the peripheral tube 136 into the chamber 134 within the inflatable flow divider 110. The fluid then passes through the mesh or porous region 132 of the flow divider 110 to perfuse the aorta. Preferably, the apertures 138 of the peripheral tube 136 are sized so that the pressure within the peripheral tube 136 is higher than the pressure within the chamber 134 of the flow divider 110.

The porous and non-porous sections of the flow divider 110 may be formed from the same or separate materials. Suitable materials for the non-porous portions of the flow divider

110 include, but are not limited to, elastomers, thermoplastic elastomers, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers, and reinforced composites thereof. Suitable materials for the porous portions of the flow divider 110 include meshes, woven and nonwoven fabrics, and porous membranes, such as microperforated or laser perforated polymer or elastomer films. For example, polyester meshes may be used, such as meshes made by Saati Corporations and Tetko, Inc. These are available in sheet form and can be easily cut and formed into a desired shape. Other meshes and porous materials known in the art, which have the desired characteristics, are also suitable.

Referring to FIG 19, an embodiment of the flow divider 110 is disclosed having a nonporous film 140 surrounded by a peripheral tube 136 acting as a support structure. Inflation of the peripheral tube 136 causes deployment of the film 140 within the aorta. Holes are positioned over the perfusion apertures 118 to allow perfusion of the region above the flow divider 110. FIG 20 is a cross section view of the flow divider 110 of FIG 19 taken along line 20-20. It is possible to make the flow divider 110 of FIG 19 by fabricating an oval balloon and affixing the central portion of the top and bottom layers together, leaving a peripheral region where the upper and lower layers are not coupled together forming the inflatable peripheral tube 136. Alternatively, the peripheral tube 136 and film 140 of the flow divider 110 may be formed of separate components and affixed together by a known means for joining such materials, such as by heat welding or adhesives.

FIGS 21-23 represent alternate embodiments of the flow divider 110 with welds or joined areas 142 between an upper and a lower film of the flow divider 110 to give additional structure and rigidity to the flow divider 110. FIG 21 discloses an embodiment wherein the interior surface of the upper film has been coupled to the interior surface of the lower film, preferably by spot heat welding or adhesive. The resulting structure maintains the geometry of the flow divider 110 and provides it with additional rigidity. FIG 22 is a cross section view of the flow divider 110 of FIG 21 taken along line 22-22. FIG 23 shows an alternate embodiment of FIG 21 with larger joined areas 142 between the upper and lower films of the flow divider 110 creating well defined peripheral tube 136 and lateral or branch support members 144. In alternative embodiments, the film 140 and peripheral tube 136 and lateral or branch support members 144 may be fabricated as separate components and joined using any known means for doing so, including the use of adhesive or heat welding.

FIGS 24-26 disclose embodiments of the flow divider 110 that are deployed by extending one or more preshaped deployment wires 146, 148 from within the catheter 100. FIG 24 shows an embodiment that employs two wires for deployment. This embodiment includes a nonporous film 140 surrounded by a peripheral tube 136 in which the deployment wires 146 and 148 reside. The deployment wires 146, 148 are coupled at one end to the distal end the catheter shaft at points 152. The deployment wires 146, 148 pass through one lumen, or alternatively two parallel lumens, from the proximal end 104 of the catheter 100 to the distal region of the catheter, and through deployment wire apertures 150 to the external surface of the distal region of the catheter 100. In the non-deployed state, the flow divider 110 is preferably folded tightly against the exterior of the catheter shaft 102 so that the outer diameter of the folded flow divider 110 is not much larger than the diameter of the catheter shaft 102. The flow divider 110 is deployed by pushing the proximal end of the deployment wires 146, 148 through lumens into the catheter shaft. As the deployment wires 146, 148 are extended from within the catheter 100, the deployment wires 146, 148 cause the flow divider 110 to deploy. The deployment wires 146, 148 are preferably preshaped to assume the desired configuration. Suitable materials for the deployment wires 146, 148 include, but are not limited to, stainless steel, cobalt alloys, nickel-titanium alloys and highly radiopaque materials, such as platinum, tantalum or tungsten alloys. FIG 25 is a cross section view of the divider of FIG 24 taken along line 25-25, and shows the deployment wires 146, 148 within the peripheral tube 136 of the deployed flow divider 110. In an alternate embodiment, as seen in FIG 26, the flow divider 110 may be sack-like with the deployment wires 146, 148 preshaped to hold the flow divider 110 in an open or deployed configuration.

FIG 27 discloses an alternate embodiment of a flow divider 110 requiring only a single deployment wire 154. In this embodiment, the deployment wire 154 is not coupled to the distal end 106 of the catheter 100. Instead, the end of the deployment wire 154 is threaded through the peripheral tube 136 in a clockwise or counterclockwise direction. The deployment wire 154 is preferably preshaped to assume the desired configuration and includes a rounded end 156 for better tracking and to prevent the deployment wire 154 from puncturing the flow divider 110.

It will also be understood from FIGS 23-27 that the flow divider 110 may be constructed with the deployment wire(s) permanently fixed in a deployed position. For

example, the distal portions of the deployment wires 146, 148 in FIG 24 may constitute two permanently deployed side support wires for the flow divider 110, or the distal portion of the single deployment wire 154 of FIG 27 may be configured into a continuous support loop within the flow divider 110. In addition, the deployment wire(s) may be bonded to the flow divider 110, such as by heat sealing or adhesive bonding. The flow divider 110 in this case would be collapsed by elastic deformation of the deployment wire(s), for example by withdrawing the flow divider 110 into a catheter, cannula or introducer sheath, rather than by retraction of the deployment wire(s). Optionally, the proximal portions of the deployment wire(s) that extend through the catheter shaft 102 may be dispensed with. In other alternate constructions, movable or permanently fixed deployment wire(s) may be combined with one or more inflatable chambers for additional support of the flow divider 110.

FIG 28 discloses a perspective view of an embodiment of the catheter of the invention wherein the flow divider 110 comprises a shroud 164 deployed by means of movable ribs or arms 162. The flow divider 110 seen in FIG 28 comprises a plurality of mechanical pivot arms 162 with a film or web-like shroud 164 bonded to the catheter shaft 102 and the pivot arms 162. The pivot arms 162 may be mechanically extended, but in alternate embodiments, fluid pressure may be used to pivot the arms 162. In other alternate embodiments, the pivot arms 162 may instead be hollow tubes, which are extended by filling them with fluid under pressure. When the pivot arms 162 are extended, the shroud 164 unfolds, and the flow divider 110 is deployed. FIG 29 shows the flow divider 110 of FIG 28 in a collapsed or undeployed state with the pivot arms 162 pivoted against the catheter shaft 102, and the shroud 164 folded against the catheter shaft 102. FIG 30 shows a top view of the flow divider 110 in a deployed configuration. Once deployed, this embodiment of the flow divider 110 is used in the same way as the flow dividers previously described.

Most of the previously described flow divider 110 embodiments have been deployed from the external surface of a catheter shaft. However, in other embodiments, the flow divider 110 may be deployed from within one or more lumens in a catheter shaft. For example, FIG 31 discloses a flow divider 110 deployed within an aorta B, and coupled to a deployment wire 170 that is extended from a lumen with an opening in the distal end 106 of the catheter shaft 102. The flow divider 110 is preferably comprised of a material or materials with a shape memory, so that the flow divider 110 will assume the desired configuration on release from the catheter shaft 102. Any known suitable materials may be used including, but not limited

to, elastomers, thermoplastic elastomers, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers, and reinforced composites thereof. In some embodiments, the flow divider 110 may include lateral or branch stiffeners to assist the flow divider 110 in maintaining a desired configuration or shape. Alternatively, the flow divider 110 may be deployed with movable or permanently fixed deployment wire(s) or with a continuous support loop, as described above in connection with FIGS 23-27. Perfusion of the arch vessels in this embodiment, may be provided by another perfusion source, such as a second catheter. FIG 32 is a cross section view of the flow divider 110 of FIG 31 taken transversely through the aorta B showing a preferred position of the flow divider 110 within the aorta B.

FIG 33 illustrates an alternate embodiment of the flow divider 110 of FIG 31. In this embodiment, the flow divider 110 includes a stiff spine 172 extending along the length of the flow divider 110 with a deployment wire 170 coupled to the spine 172 at a point intermediate the ends of the spine 172. The flow divider 110 may include additional stiffening structures if desired. The flow divider 110 may be used independently or it may be deployed through a catheter 100. The flow divider 110 is deployed by pushing the flow divider 110 out of a lumen having an opening near the distal end 106 of the catheter 100. The catheter 100 may then be advanced until the distal end 106 of the catheter 100 is proximate the point 174 at which the deployment wire 170 is coupled to the spine 172 of the flow divider 110, as shown in FIG 34. The catheter 100 may include additional perfusion ports 118 near the distal end 106 of the catheter 100 to perfuse the region above the flow divider 110. FIG 35 shows an embodiment of the flow divider 110 being withdrawn. In some embodiments withdrawal of the flow divider 110 may be accomplished by pulling the flow divider 110 into the lumen of the catheter 100. The flow divider 110 may bend at the connection point between the deployment wire 170 and the flexible spine 172. FIG 36 shows an alternate embodiment including a tether wire 176 coupled to the proximal end 122 of the flow divider 110 nearest the catheter 100. In this embodiment, the catheter 100 need not be bent to be withdrawn. Instead, the flow divider 110 is withdrawn by pulling the tether wire 176. This aligns the end of the flow divider 110 with the opening of the lumen into which the flow divider 110 will be withdrawn, as seen in FIG 37.

FIGS 38–40 illustrate an embodiment of the flow divider 110 comprising a plurality of flexible arms 180 extending from a spine or inner catheter 184 with a shroud or web 182 extending between the flexible arms 180. The flow divider 110 is deployed from a lumen

within the catheter shaft 102 from an opening at the distal end 106 of the catheter shaft 102. FIG 38 shows the flow divider 110 deployed within the aortic lumen B. The flexible arms 180 are arrayed extending outward from the shaft of the flow divider 110, supporting the shroud or web 182 between the extended flexible arms 180. FIG 39 shows the flow divider 110 of FIG 38 disposed in an undeployed state within the catheter shaft 102. FIG 40 shows the flow divider 110 partially deployed from within the catheter shaft 102. As the flow divider 110 is pushed from the distal end 106 of the catheter 100, the flexible arms 180 spring outward, deploying the shroud or web 182 between the flexible arms 180. The flow divider 110 is withdrawn by pulling the flow divider 110 into the catheter shaft 102. The flexible arms 180 fold again, but in the opposite direction. In an alternate embodiment, the flow divider 110 may be coupled to the exterior surface of the catheter shaft 102, and a sheath may be slid over the flow divider 110 in its undeployed configuration. The divider may then be deployed by sliding the sheath along the catheter shaft 102 to expose the flow divider 110. In another alternative embodiment, the flexible arms 180 may be pivotally attached to the inner catheter 184, and the flow divider 110 may be mechanically deployed and retracted by deployment wires (not shown) within the inner catheter 184. In yet another alternative embodiment, the flexible arms 180 may be inflatable and deflatable to deploy and retract the flow divider 110.

FIGS 41 and 42 illustrate an embodiment of the flow divider 110 comprising a flexible tongue that is folded back within the catheter shaft 102 and deployed using a deployment wire 186 to push the flow divider 110 out. Referring to FIG 41, the proximal end of the flow divider 110 is coupled to the distal end 106 of the catheter shaft 102 at point 188. Deployment is accomplished by using a deployment wire 186 to push the flow divider 110 out of the lumen in the catheter shaft 102. The dotted lines 110' show intermediate positions of the flow divider 110 as it is deployed. FIG 42 shows the flow divider 110 of FIG 41 fully deployed and with the deployment wire 186 retracted. Once the deployment wire 186 is removed, the aorta above the upper surface of the flow divider 110 can be perfused through the same lumen used by the deployment wire 186.

FIGS 43A-F, 44A-C and 45A-B show an aortic catheter 200 with a flow divider 210 configured for performing differential perfusion of a patient's circulatory system. FIG 43A shows a perspective view of the aortic catheter 100. In this illustrative example, the aortic catheter 200 is configured for central introduction into the aortic arch through an aortotomy in the ascending aorta. The aortic catheter 200 could alternatively be configured for introduction

via peripheral arterial access. The flow divider 210 is mounted on a distal portion of an elongated catheter shaft 202. The catheter shaft 202, shown in cross section in FIG 43D, is constructed with three lumens: an arch perfusion lumen 204, a corporeal perfusion lumen 206 and an inflation lumen 208. The arch perfusion lumen 204 extends through the catheter shaft 202 and communicates on its distal end with one or more arch perfusion ports 212, which are located on an upper surface 214 of the flow divider 210. The proximal end of the arch perfusion lumen 204 connects to an arch perfusion extension tube 216, shown in cross section in FIG 43B, which terminates in an arch perfusion connector 218, such as a barb fitting with a Luer-lock side branch or the like. The corporeal perfusion lumen 206 extends through the catheter shaft 202 and communicates on its distal end with a corporeal perfusion port 220, which is located near the distal end of catheter shaft 202 and preferably below the flow divider 210. The proximal end of the corporeal perfusion lumen 206 connects to a corporeal perfusion extension tube 224, shown in cross section in FIG 43C, which terminates in a corporeal perfusion connector 226, such as a barb fitting with a Luer-lock side branch or the like.

The inflation lumen 208 extends through the catheter shaft 202 and connects on its distal end with an inflation port 228, shown in FIGS 44B and 44C, which communicates with the interior of the inflation chamber 230 of the flow divider 210. The proximal end of the inflation lumen 208 connects to, or is continuous with, an inflation lumen extension tube 232, which terminates in an inflation lumen connector 234, such as a stopcock with a Luer-lock connector or the like. A manifold cover 236, which is preferably an injection molded part, covers and reinforces the junction where the catheter shaft 202, the arch perfusion extension tube 216, the corporeal perfusion extension tube 224 and the inflation lumen extension tube 232 join together. Preferably, the aortic catheter 200 includes an inflation indicator 238 on the inflation lumen extension tube 232. The inflation indicator 238 is a small, low-pressure balloon that is mounted on the inflation lumen extension tube 232, such as by heat sealing or adhesive bonding. The interior of the inflation indicator 238 is connected to the inflation lumen 208 by an inflation indicator port 240 on the inflation lumen extension tube 232. The inflation indicator 238 inflates to provide a visual indication whenever the flow divider 210 is inflated.

The catheter shaft 202 may be formed as a multilumen extrusion or it may be formed as a composite construction made up of individual tubes. In one particularly preferred construction, the catheter shaft 202 is constructed by joining together three individual tubes representing the arch perfusion lumen 204, the corporeal perfusion lumen 206 and the

inflation lumen 208. FIG 43E shows an exploded view of the composite construction catheter shaft 202. FIG 44C shows the catheter shaft 202 with the flow divider 210 removed to illustrate the composite construction more clearly. The corporeal perfusion lumen 206 is constructed as a D-shaped tube 246, which is preferably reinforced over its entire length with a wire coil 248. Similarly, the arch perfusion lumen 204 is constructed as a D-shaped tube 242, which is reinforced over at least part of its length with a wire coil 244. The wire coil 244 reinforcing the D-shaped tube 242 for the arch perfusion lumen 204 preferably extends from the proximal end of the catheter shaft 202 to an intermediate point located under the proximal end of the flow divider 210, and the D-shaped tube 242 continues unreinforced to the distal end of the catheter. A plastic filler plug 254 may be inserted into the distal end of the D-shaped tube 242 to terminate and seal the arch perfusion lumen 204. The inflation lumen 208 is constructed as a single lumen tube 250, which, as noted above, may be continuous with the inflation lumen extension tube 232. The three tubes 242, 246, 250 are then covered with a clear, thin-walled heat shrink tube 252 and heated to create the composite construction shown in FIG 43D. One or more arch perfusion ports 212 are cut or drilled through the unreinforced wall of the arch perfusion lumen 204 in the distal portion catheter shaft 202.

A gentle S-shaped curve is set into the catheter shaft 202 by placing the catheter shaft 202 on a curved mandrel and heating it. The distal portion of the catheter shaft 202 where the flow divider 210 will be mounted is given a curve that approximates the internal curvature of a human aortic arch. A suture ring 268 is attached to the exterior of the catheter shaft 202 slightly proximal to where the flow divider 210 will be mounted. Preferably, the suture ring 268 is mounted slightly obliquely on the catheter shaft 202, as shown in FIG 44C, so that it will lie flat against the outer wall of the aorta when the curved catheter shaft 202 is inserted through an aortotomy incision into the ascending aorta.

FIGS 45A-B show a top and bottom view of a distal end portion of the aortic catheter 200 of FIG 43A showing the flow divider 210 in a deflated condition. FIG 44A shows a side perspective view of the flow divider 210 in an inflated condition. FIG 44B shows a cutaway side perspective view and FIG 43F shows a lateral cross section of the flow divider 210 in the inflated condition. The flow divider 210 has an upper wall 214 and a lower wall 222 that enclose an inflation chamber 230. The upper wall 214 and lower wall 222 of the flow divider 210 are preferably constructed of a first and second sheet of plastic film that are joined to one another around their peripheral edges 256 and at one or more interior locations 258, for example by heat sealing or adhesive bonding. Suitable materials for the upper wall 214 and lower wall 222 of the flow divider 210 include, but are not limited to, elastomers,

thermoplastics, polyvinylchloride, polyurethane, polyethylene, polyamides, polyesters, silicone, latex, and alloys or copolymers, and reinforced composites thereof. The plastic film that makes up the upper wall 214 and lower wall 222 may have the same or different thicknesses. For example, the upper wall 214 may be made of a thinner plastic film than the lower wall 222.

The flow divider 210 is generally an elongated oval shape that is sized to fit within the lumen of a patient's aortic arch. In one particularly preferred embodiment, the upper wall 214 of the flow divider 210 is slightly larger in length and width than the lower wall 222. When the peripheral edges 256 of the upper wall 214 and lower wall 222 are heat sealed together, this creates a pair of longitudinal folds or wrinkles 260, 262 and at least one lateral fold or wrinkle 264 in the upper wall 214 when the flow divider 210 is deflated, as seen in the top view in FIG 45A. These folds or wrinkles 260, 262, 264 create flow channels that assist the flow divider 210 to deflate fully.

The interior seals 258 of the flow divider 210 are located so that they will cover the arch perfusion ports 212 in the distal portion of the catheter shaft 202. D-shaped holes 266 are cut through the interior seals 258 to coincide with each of the arch perfusion ports 212. Once the flow divider 210 is formed, it is adhesively bonded to the distal portion of the catheter shaft 202 with the D-shaped holes 266 positioned over the arch perfusion ports 212 so that the distal or downstream side of each arch perfusion port 212 is covered. The distal end of the single lumen tube 250 is connected to the flow divider 210 so that the inflation lumen 208 communicates with the inflation chamber 230 through the inflation port 228.

Typically, the flow divider 210 will be attached symmetrically on the catheter shaft 202, as shown in FIGS 45A-B. When the aortic catheter 200 is insert through an aortotomy incision located along the centerline of the ascending aorta, the flow divider 210 will be centered within the lumen of the aortic arch. However, for surgeons who prefer to place the aortotomy incision closer to the anterior wall of the ascending aorta, this configuration may result in the flow divider 210 being off center within the aortic arch. To facilitate this alternate surgical technique, an alternative construction of the aortic catheter 200 is shown in FIG 46, with the flow divider 210 attached asymmetrically on the catheter shaft 202. This configuration facilitates correct placement of the flow divider 210 within the aortic arch. When this aortic catheter 200 is insert through an aortotomy incision located near the anterior wall of the ascending aorta, the asymmetrically mounted flow divider 210 will be centered within the lumen of the aortic arch.

Prior to use, the flow divider 210 is deflated and tightly wrapped around the catheter shaft 202. This reduces the profile of the aortic catheter 200 and helps to straighten the distal curve of the catheter shaft 202 slightly, which facilitates insertion of the aortic catheter 200 through an aortotomy incision. When it is inflated, the flow divider 210 unwraps from the catheter shaft 202 and assumes a somewhat flattened shape that follows the distal curve of the catheter shaft 202. The sealed peripheral edge 256 of the flow divider 210 creates a flexible skirt around the periphery of the flow divider 210 that helps to form a fluid flow seal between the flow divider 210 and the aortic wall.

The patient's corporeal circulation may be perfused with blood or other fluids through the corporeal perfusion lumen 206 and the aortic arch vessels may be separately perfused through the arch perfusion lumen 204. The D-shaped holes 266 over the arch perfusion ports 212 tend to diffuse the fluid flow exiting the arch perfusion ports 212 and direct it somewhat in the upstream direction. This helps to eliminate high velocity jetting, which could dislodge plaques, thrombus or other potential embolic materials. Any of the various other embodiments of the flow divider described herein may be similarly modified to perform differential perfusion by addition of a corporeal perfusion lumen for perfusing the corporeal circulation separately from the cerebral circulation.

FIGS 47A-B and 48A-B shows an aortic catheter 300 with a flow divider 302 having a lower support member 304 for supporting the flow divider 302 within a patient's aortic arch. Generally speaking, the aortic catheter 300 and flow divider 302 may be constructed according to any of the various embodiments described herein. By way of example, aortic catheter 300 the flow divider 302 is shown constructed with an inflatable configuration. The flow divider 302 has an upper membrane 306 that is attached to a catheter shaft 308. An upper inflatable chamber 310 surrounds and supports the upper membrane 306. An arch perfusion lumen 314 communicates with one or more arch perfusion ports 312 that exit the catheter shaft 308 above the flow divider 302. A corporeal perfusion lumen 322 communicates with a corporeal perfusion port 324 located near the distal end of the catheter shaft 308. The lower support member 304 has a lower membrane 318 and a lower inflatable chamber 316 that extend downward from the catheter shaft 308. The lower inflatable chamber 316 may be independently inflatable or it may be inflated through a common inflation lumen that connects to both the upper inflatable chamber 310 and the lower inflatable chamber 316. Optionally, the aortic catheter 300 may also include an auxiliary flow control member 320, such as an

inflatable occlusion balloon, mounted on the catheter shaft 308 upstream of the flow divider 302.

FIGS 48A-B show the aortic catheter 300 of FIG 47A deployed within a patient's aortic arch. The flow divider 302 is deployed by inflating the upper inflatable chamber 310 to extend the upper membrane 306 to separate the aortic blood flow into a first channel and a second channel. The lower support member 304 is deployed by inflating the lower inflatable chamber 316 so that the lower support member 304 contacts the inferior wall of the aortic arch, thereby supporting the flow divider 302 at the correct position within the aorta.

Such a flow divider having a lower support member may be used with aortic catheters configured for central or peripheral introduction. However, the additional support provided by the lower support member may be especially advantageous for aortic catheters that are introduced via the femoral artery. Other configurations of flow dividers with lower support members are possible, as shown by the following examples.

FIG 49 shows an aortic catheter 330 with a flow divider 332 configured for femoral artery introduction and having a pigtail distal end 334 on the catheter shaft 336 for supporting the flow divider 332 within a patient's aortic arch. The large diameter pigtail distal end 334 may be straightened out with a guidewire or the like for introduction into the vascular system. Once the aortic catheter 330 is positioned within a patient's aortic arch, the flow divider 332 is deployed by inflation or other means, and the pigtail distal end 334 is deployed as a support member by withdrawing the guidewire to allow the pigtail distal end 334 to resume its curvature. The pigtail distal end 334 contacts the inferior wall of the aortic arch, thereby supporting the flow divider 332 at the correct position within the aorta. In an alternative construction, the pigtail distal end 334 may be provided by a separate catheter or guidewire that is inserted through a lumen within the aortic catheter 330.

FIG 49 illustrates another optional feature that may be used with this or any of the flow dividers described herein. A multiplicity of small radiopaque markers 338 are placed around the periphery of the flow divider 332 for fluoroscopically monitoring the position and the deployment state of the flow divider 332. The radiopaque markers 338 may be adhesively attached to the flow divider or they may be heat sealed between the layers of the flow divider during assembly.

FIG 50 shows an aortic catheter 340 with a flow divider 342 configured for femoral artery introduction and having an extendable lower support member 346 for supporting the flow divider 342 within a patient's aortic arch. The extendable lower support member 346 is

constructed with a wire 348 that has been heat treated or cold worked to assume a circular or helical configuration when it is unconstrained. A distal end of the wire 348 is attached near the distal end of the catheter shaft 344. The lower support member 346 is compressed for easier introduction into the patient's vascular system by withdrawing the wire 348 into the catheter shaft 344 to straighten it out. Once the aortic catheter 340 is positioned within a patient's aortic arch, the flow divider 342 is deployed by inflation or other means, and the lower support member 346 is deployed by advancing the wire 348 from the catheter shaft 344 so that it resumes its curvature. The lower support member 346 contacts the inferior wall of the aortic arch, thereby supporting the flow divider 342 at the correct position within the aorta.

FIG 51 shows an aortic catheter 350 with an auxiliary flow control member 354 positioned at an upstream end of the flow divider 352. The auxiliary flow control member 354 is in the form of an inflatable balloon mounted on the underside of the flow divider 352 near its upstream end. When inflated, the auxiliary flow control member 354 is capable of fully occluding the lumen of the ascending aorta for inducing cardioplegic arrest and implementing cardiopulmonary bypass with differential perfusion of the aortic arch vessels. When deflated, the auxiliary flow control member 354 collapses against the lower surface of the flow divider 352. This configuration shortens the overall length of the flow divider 352 and auxiliary flow control member 354 assembly, as compared with the configuration shown in FIGS 13-14, making it especially suitable for central introduction through an aortotomy into the ascending aorta. Optionally, the aortic catheter 350 may include a cardioplegia lumen that exits the catheter 350 upstream of the auxiliary flow control member 354.

FIG 52 shows an aortic catheter 360 with an auxiliary flow control member 364 in the form of an inflatable balloon positioned near the center of the flow divider 362. When deflated, the auxiliary flow control member 364 collapses against the lower surface of the flow divider 362. When inflated, the auxiliary flow control member 354 occludes the lower half of the aortic lumen within the aortic arch, while the flow divider 362 isolates the aortic arch vessels from the rest of the circulatory system. This configuration allows isolation of the coronary arteries for inducing cardioplegic arrest and implementing cardiopulmonary bypass with differential perfusion of the aortic arch vessels. The inflated auxiliary flow control member 364 also provides support for the flow divider 362 within the aortic lumen. Optionally, the aortic catheter 360 may include a cardioplegia lumen that exits the catheter 360 upstream of the auxiliary flow control member 364.

FIG 53 shows an aortic catheter 370 having a flow divider 372 with an aortic filter assembly 374 for capturing embolic material in the aortic blood flow. The flow divider 372 may be constructed according to any of the various embodiments described herein. The aortic filter assembly 374 has a filter support member 376 that supports the open upstream end of a filter mesh 378. The filter support member 376 is approximately semicircular and is attached to the underside of the flow divider 372. The filter support member 376 may be an inflatable support member that is separately or commonly inflatable with an inflatable flow divider 372. Alternatively, the filter support member 376 may be a flexible wire that deploys by elastic memory. The filter mesh 378 is approximately semi-conical in shape and is attached along its lateral edges to the flow divider 372. The filter mesh 378 may be a course filter mesh for capturing macroemboli or a fine filter mesh for capturing microemboli and macroemboli. The flow divider 372 isolates the aortic arch vessels allowing differential perfusion of the cerebral circulation and the aortic filter assembly 374 captures emboli in the aortic blood flow before they enter the corporeal circulation.

FIG 54 shows an aortic catheter 270 having a flow divider 278 with an arch perfusion filter 274 deployed within a patient's aortic arch. FIG 55 is a distal end view the flow divider 278 of FIG 54 with the catheter shaft 280 shown in cross section. The flow divider 278 is mounted on an elongated catheter shaft 280. An inflation lumen 276 within the catheter shaft 280 communicates with the interior of the flow divider 278. A corporeal perfusion lumen 286 within the catheter shaft 280 communicates with a corporeal perfusion port 272 near the distal end of the catheter shaft 280. An arch perfusion lumen 284 within the catheter shaft 280 communicates with one or more arch perfusion ports 282 that exit the catheter shaft 280 above the flow divider 278. An arch perfusion filter 274 is attached to the upper surface of the flow divider 278 and covers the arch perfusion ports 282. The arch perfusion filter 274 filters the blood that is perfused to the aortic arch vessels, guarding against any potential emboli.

FIG 56 shows an aortic catheter 290 having a flow divider 292 with fiberoptic illumination for monitoring the location and deployment state of flow divider 292 by aortic transillumination. The flow divider 292 may be constructed according to any of the various embodiments described herein. An optical fiber 296 extends through the aortic catheter 290 to the flow divider 292. The proximal end of the optical fiber 296 is adapted for connection to a light source 298. A distal portion of the optical fiber 296 is treated to create a light emitter

294. The light emitter 294 may be created by removing the cladding from a clad optical fiber and/or by scratching or faceting the surface of the optical fiber 296 to allow light to escape from the optical fiber 296. The light emitter 294 is preferably located around the peripheral edge of the flow divider 292. The light emitted from the optical fiber 296 through the light emitter 294 is visible through the wall of the aorta and allows the surgeon to monitor the position and the deployment state of flow divider 292 within the aorta without the need for fluoroscopy or ultrasonic imaging.

FIG 57 shows an aortic catheter 400 with a flow divider 402 being inserted into a patient's aortic arch. FIG 58 shows the flow divider 402 of FIG 57 deployed within the patient's aortic arch. The aortic catheter 400 has an introducer cannula 404 with an internal lumen 412. The flow divider 402 has an internal support wire 406 that is preferably made of a highly resilient material, such as a nickel-titanium alloy, stainless steel or a cobalt alloy. The support wire 406 forms a loop that follows the periphery of the flow divider 402. The flow divider 402 may be formed as a loose envelope of polymeric film surrounding the support wire 406 or, alternatively, the flow divider 402 may be formed of two layers of polymeric film heat sealed together to capture the support wire 406 between them. Optionally, the flow divider 402 may be made with a flexible skirt 416 around the periphery to help create a seal against the aortic wall. The support wire 406 is connected to a slide actuator 410 on the cannula 404 by an actuation member 408 that passes through the internal lumen 412. The actuation member 408 may be a continuation of the support wire 406. In FIG 58, the flow divider 402 is withdrawn into the internal lumen 412 of the cannula 404 to facilitate insertion of the aortic catheter 400 through an aortotomy incision by moving the slide actuator 410 proximally along a slot 414 in the cannula 404. Once the aortic catheter 400 is in place within the patient's aortic arch, the slide actuator 410 is moved distally along the slot 414 to deploy the flow divider 402 within the aortic arch, as shown in FIG 58.

Once deployed within the patient's aortic arch, the flow divider 402 provides protection from embolic materials in the aortic blood flow entering the cerebral circulation. Perfusion to the aortic arch vessels may be provided by a separate perfusion cannula introduced into the aorta above the flow divider 402. Alternatively, the patient's aortic arch vessels may be perfused in a retrograde manner through a perfusion cannula inserted into the right axillary or subclavian artery. If total bypass is desired, corporeal perfusion may be provided through a corporeal perfusion cannula inserted into the aorta or through a peripheral vessel, such as a femoral artery.

FIG 59 shows an aortic catheter 420 having a flow divider 422 with an internal support wire 424 configured for differential perfusion of a patient's circulatory system. The support wire 424 is formed as a loop of highly resilient material that is connected to a slide actuator 426 on the catheter body 428. Moving the slide actuator 426 in a proximal direction contracts the support wire loop 424 or withdraws it into the catheter shaft 444, allowing the flow divider 422 to collapse. Moving the slide actuator 426 in a distal direction extends the support wire loop 424 to deploy the flow divider 422. In an alternate construction, the support wire 424 may be a fixed loop and the flow divider 422 may be actuated by inflating an inflation chamber within the flow divider 422. An arch perfusion lumen 430 communicates with one or more arch perfusion ports 432 located above the flow divider 422 and a corporeal perfusion lumen 434 communicates with one or more corporeal perfusion ports 436 located below the flow divider 422, allowing differential perfusion of the patient's cerebral and corporeal subcirculations.

FIG 60 shows the aortic catheter 420 of FIG 59 with the additional feature of an auxiliary flow control member 438 in the form of an inflatable occlusion balloon. The auxiliary flow control member 438 is mounted on the underside of catheter shaft 444 upstream from the flow divider 422. An inflation lumen 440 having a stopcock with a Luer-lock connector or the like communicates with the interior of the auxiliary flow control member 438. When inflated, the auxiliary flow control member 438 occludes the lumen of the ascending aorta for procedures involving cardioplegic arrest and full cardiopulmonary bypass.

FIG 61 shows the aortic catheter 420 of FIG 59 with the additional feature of a selectively deployable aortic filter 450, which includes a filter support member 452 and a filter mesh 454. The filter support member 452 is an approximately circular loop of highly resilient wire that is connected by an actuator member 456 to a filter slide actuator 458 on the catheter body 428. The filter mesh 454 may be a course mesh for capturing macroemboli or a fine mesh for capturing microemboli and macroemboli and may be conical, hemispherical or any other convenient shape. The open upstream end of the filter mesh 454 is attached to the filter support member 452. The aortic filter 450 is deployed by moving the filter slide actuator 458 distally to extend the filter support member 452 from the underside of the catheter shaft 444 upstream of the flow divider 422 to open the filter mesh 454 within the ascending aorta. The aortic filter 450 may be deployed throughout the duration of a surgical procedure or it may be selectively deployed at times of high risk for embolization, such as during application or release of an aortic cross clamp. When the aortic filter 450 is no longer needed, the filter

slide actuator 458 is moved proximally to retract the filter support member 452 and the filter mesh 454 into the catheter shaft 444. The filter support member 452 may be arranged so that it closes the filter mesh 454 like a purse string upon withdrawal to positively capture any embolic materials contained therein.

In one method of use, the aortic catheter of any of the embodiments described above may be introduced into the patient's circulatory system through a peripheral artery access such as the femoral artery, by the percutaneous Seldinger technique, through an introducer sheath, or via an arterial cutdown. Referring more specifically to FIG 5, the catheter 100 is advanced up the descending aorta and across the aortic arch, under fluoroscopic or ultrasound guidance with the aid of a guidewire within the guidewire lumen 114. The aortic catheter 100 is advanced until the flow divider 110 is positioned in the aortic arch. This may be determined by reference to the location markers 116. The divider 110 is then deployed, dividing the aortic lumen into two flow channels. Using a multihead cardiopulmonary bypass pump or the like, perfusion of oxygenated blood is started through the perfusion ports 118 to perfuse the flow channel above the flow divider 110, and thereafter to perfuse the arch vessels. Blood from the heart is directed through the flow channel below the flow divider 110. At the completion of the surgical procedure, and after the majority of embolic material has passed harmlessly beyond the arch vessels, the divider 110 is retracted or allowed to collapse. The aortic lumen is then no longer divided into two flow channels, and oxygenated blood is allowed to flow from the heart to the arch vessels. The patient is then weaned off of bypass, and the catheter 100 and other cannulas are withdrawn.

In an alternative method, a catheter embodiment configured for antegrade deployment, such as those shown in FIGS 15 and 16, would be used similarly, except that access to the patient's circulatory system would be made through a central access by an aortotomy or incision directly into the ascending aorta. The aorta may be accessed through a median sternotomy or other thoracotomy using standard open-chest or minimally invasive surgical techniques.

Either method may be used with the heart beating or with the heart arrested, for example, by cardioplegic arrest. When used on an arrested heart, the method may include the additional steps of occluding the ascending aorta with a cross clamp or using an auxiliary flow control member, as shown in FIG 13, and infusing a cardioplegic agent into the aortic root upstream from the auxiliary flow control member through a lumen in the catheter or through a separate cannula, or into the coronary arteries via retrograde infusion.

Another alternative method uses a multilumen catheter with a flow divider for performing differential perfusion of the patient's cerebral and corporeal subcirculations. A multilumen catheter 200, such as the one shown in FIG 43A, is deployed within a patient's aortic arch via central or peripheral access. The aortic arch vessels, which are isolated above the flow divider 210, are perfused with blood or other fluids through the aortic perfusion lumen 204, while the corporeal circulation is perfused through the corporeal perfusion lumen 206. Differential perfusion may be performed with a beating heart or a stopped heart and may be combined with cardioplegic arrest.

Any one of the above-described methods may be used for protecting a patient's cerebral circulation from potential embolization during surgery or other times. Likewise, these methods may be used for performing therapeutic hypothermia of the cerebral circulation. When timely administered, therapeutic hypothermia can greatly reduce the damaging effects to neural tissues from an embolic stroke or other cerebral ischemic event.

Modification of the operational characteristics or procedures set forth above for use in vessels other than the aorta for perfusion of blood to branch vessels, or for use of other catheter configurations disclosed herein, are readily ascertainable by those skilled in the art in view of the present disclosure.

CLAIMS

What is claimed is:

1. A fluid flow divider for dividing fluid flow within a body lumen into at least two channels, the fluid flow divider comprising a first end and a second end, a top surface and a bottom surface, and the flow divider having a deployed state wherein the flow divider divides fluid flow through the body lumen into a first flow channel and a second flow channel.

2. The fluid flow divider of claim 1, wherein the first flow channel is defined by a portion of the circumference of the walls of an aortic lumen and the top surface of the flow divider, and the second flow channel is defined by a portion of the circumference of the walls of the aortic lumen and the bottom surface of the flow divider.

3. The fluid flow divider of claim 2, wherein an upstream end of the first flow channel is substantially closed to fluid flow originating from upstream of the fluid flow divider.

4. The fluid flow divider of claim 1, further comprising a means for perfusing at least one of the channels with a fluid.

5. The fluid flow divider of claim 1, wherein fluid flow in each flow channel is substantially isolated from the fluid flow of the other flow channel by the fluid flow divider.

6. The fluid flow divider of claim 1, wherein the fluid flow divider comprises at least one inflatable chamber.

7. The fluid flow divider of claim 6, wherein the at least one inflatable chamber is configured to have a plurality of lateral support members when inflated.

8. The fluid flow divider of claim 7, wherein the at least one inflatable chamber is configured to have a peripheral support tube and a plurality of lateral support members when inflated.

9. The fluid flow divider of claim 1, wherein the fluid flow divider comprises an inflatable peripheral support tube.

10. The fluid flow divider of claim 1, further comprising a catheter having a catheter shaft with a distal end.

11. The fluid flow divider of claim 10, wherein the catheter shaft extends along the top side of the flow divider.

12. The fluid flow divider of claim 10, wherein the first end of the flow divider extends beyond the distal end of the catheter shaft.

13. The fluid flow divider of claim 10, wherein the catheter shaft extends from the top side of the flow divider, through the flow divider at a point proximate the first end of the flow divider to the bottom side of the flow divider.

14. The fluid flow divider of claim 10, wherein the distal end of the catheter shaft extends beyond the first end of the flow divider.

15. The fluid flow divider of claim 1, further comprising an embolic filter for filtering fluid flow through the body lumen.

16. The fluid flow divider of claim 10, wherein the catheter shaft extends from the bottom side of the flow divider through a point proximate the second end of the flow divider, extends along a portion of the top side of the flow divider, then extends through the flow divider at a point proximate the first end of the flow divider to the bottom side of the flow divider.

17. The fluid flow divider of claim 1, further comprising a catheter shaft having a first perfusion lumen for perfusing the first fluid flow channel with a fluid.

18. The fluid flow divider of claim 1, further comprising a catheter shaft having a first perfusion lumen for perfusing the first fluid flow channel with a fluid and a second perfusion lumen for perfusing the second fluid flow channel with a fluid.

19. The fluid flow divider of claim 18, wherein the flow divider is formed in a concave configuration.

20. The fluid flow divider of claim 10, further comprising a flow control member coupled to the catheter shaft between the distal end of the catheter shaft and the first end of the flow divider.

21. The fluid flow divider of claim 18, wherein the flow control member comprises at least one inflatable balloon.

22. The fluid flow divider of claim 18, wherein the flow control member comprises at least one deployable valve.

23. The fluid flow divider of claim 1, wherein the flow divider comprises a plurality of arms, and a webbing material extending between the catheter shaft and the plurality of arms and between adjacent pairs of the plurality of mechanically deployable arms.

24. The fluid flow divider of claim 23, wherein the plurality of arms are mechanically deployable.

25. The fluid flow divider of claim 23, wherein the plurality of arms are flexible.

26. The fluid flow divider of claim 23, wherein the plurality of arms are inflatable.

27. The fluid flow divider of claim 23, wherein the flow divider is deployable from within a catheter shaft.

28. The fluid flow divider of claim 1, wherein the fluid flow divider is configured to generate low turbulence fluid flow between a first fluid flow stream in the first fluid flow channel and a second fluid flow stream the second fluid flow channel.

29. The fluid flow divider of claim 1, wherein the fluid flow divider is configured to generate laminar fluid flow between a first fluid flow stream in the first fluid flow channel and a second fluid flow stream the second fluid flow channel.

4

30. The fluid flow divider of claim 1, wherein the fluid flow divider further comprises a permeable portion.

31. The fluid flow divider of claim 30, wherein the fluid flow divider further comprises a peripheral tube.

32. The fluid flow divider of claim 30, wherein the fluid flow divider further comprises a chamber formed between an upper film of the flow divider and a lower film of the flow divider.

33. The fluid flow divider of claim 32, wherein an interior of the peripheral tube is in fluid communication with the chamber of the fluid flow divider.

34. The fluid flow divider of claim 32, wherein at least one portion of the upper film is coupled to at least one portion of the lower film.

35. The fluid flow divider of claim 1, wherein the flow divider is deployed by extending at least one deployment wire into the flow divider.

36. The fluid flow divider of claim 35, wherein the flow divider further comprises a peripheral tube to receive the at least one deployment wire.

37. The fluid flow divider of claim 35, wherein the fluid flow divider further comprises a catheter having a catheter shaft, and wherein a distal end of the at least one deployment wire is coupled to an exterior surface of the catheter shaft.

38. The fluid flow divider of claim 10, wherein the fluid flow divider is deployed from a distal opening of a lumen within the catheter shaft.

39. The fluid flow divider of claim 38, wherein the fluid flow divider further comprises a flexible spine.

40. The fluid flow divider of claim 39, wherein the fluid flow divider further comprises lateral stiffeners.

41. The fluid flow divider of claim 1, wherein the fluid flow divider further comprises lateral stiffeners.

42. The fluid flow divider of claim 38 wherein the fluid flow divider is deployed using a deployment wire.

43. The fluid flow divider of claim 42, wherein the fluid flow divider further comprises a retraction wire.

44. A method for preventing cerebral embolization comprising deploying a fluid flow divider within an aortic lumen for dividing aortic blood flow into at least two channels, including a first channel and a second channel.

45. The method for preventing cerebral embolization of claim 44, wherein the fluid flow divider is deployed within an aortic arch.

46. The method for preventing cerebral embolization of claim 45, wherein the first channel is in fluid communication with at least one aortic arch branch vessel.

47. The method for preventing cerebral embolization of claim 46, further comprising perfusing the first channel with a fluid.

48. The method for preventing cerebral embolization of claim 47, further comprising perfusing the second channel with a fluid.

49. The method for preventing cerebral embolization of claim 44, further comprising occluding the lumen of the ascending aorta upstream of the fluid flow divider.

50. The method for preventing cerebral embolization of claim 49, further comprising infusing a cardioplegic agent into the root of the ascending aorta.

PCT

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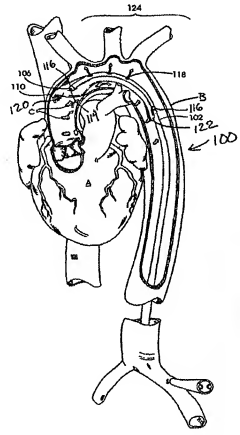
(54) Title: AORTIC CATHETER WITH FLOW DIVIDER AND METHODS FOR PREVENTING CEREBRAL EMBOLIZATION

(57) Abstract

The invention is a catheter with a fluid flow divider positioned near the distal end of the catheter for dividing a first lumen into two channels at a point where a second lumen branches from the first lumen, and for selectively perfusing the branch lumen and the first lumen. The invention is particularly suited for use in the aortic arch. The fluid flow divider may comprise one or more inflatable chambers or one or more deployable shrouds comprising a plurality of arms with a web extending between adjacent arms. The inflatable chambers may be relatively noncompliant or they may be compliant, exhibiting elastic behavior after initial inflation, to closely fit the aortic lumen size and curvature. The catheter may further include one or more additional or auxiliary flow control members located upstream or downstream from the fluid flow divider to further segment the patient's circulatory system for selective perfusion to different organ systems within the body or to assist in anchoring the catheter in a desired position. The catheter may also include a selectively deployable embolic filter for capturing embolic materials in the blood stream.



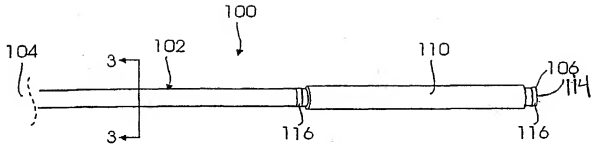


Fig 1

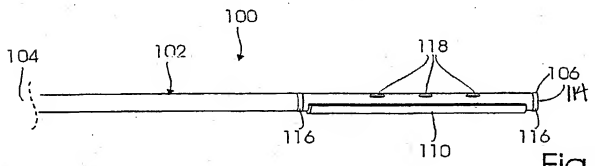


Fig 2

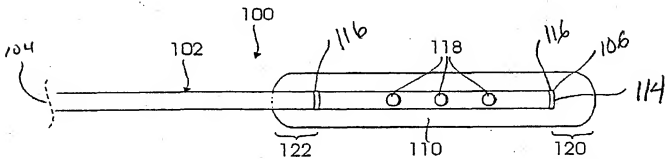


Fig 4

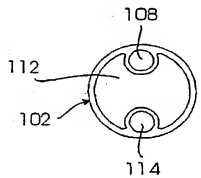


Fig 3

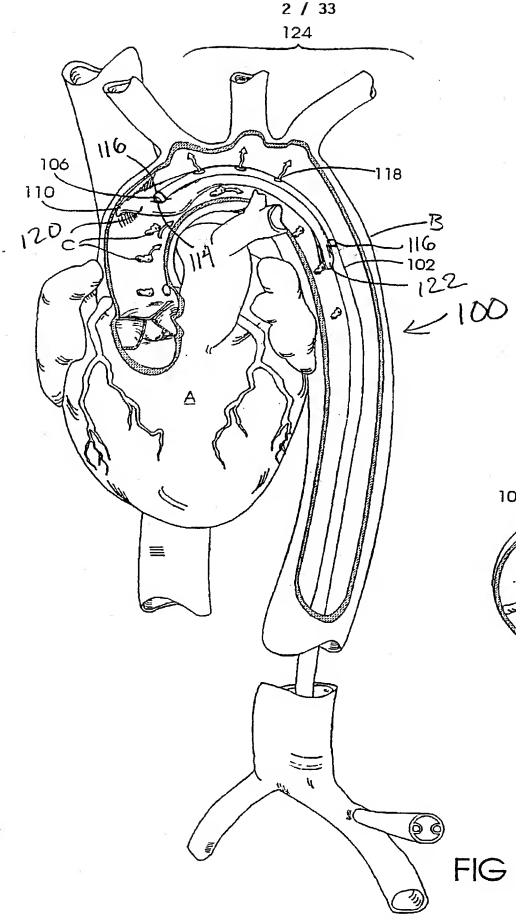

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FIG 5

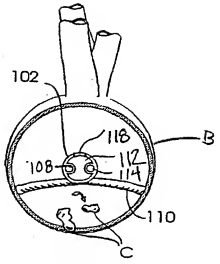
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FIG 7

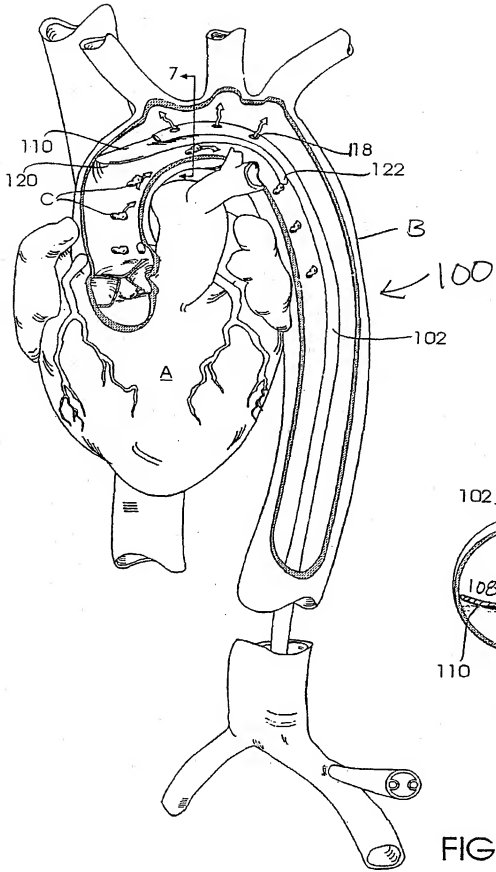

FIG 6

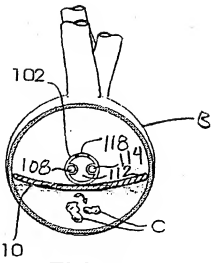

FIG 8

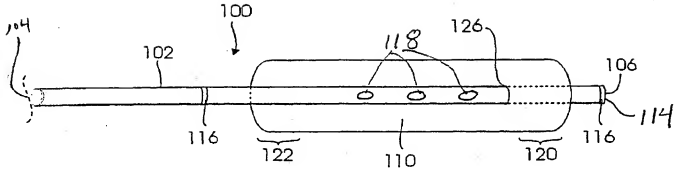
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FIG 9

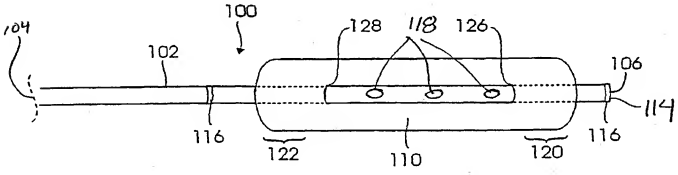
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FIG 10

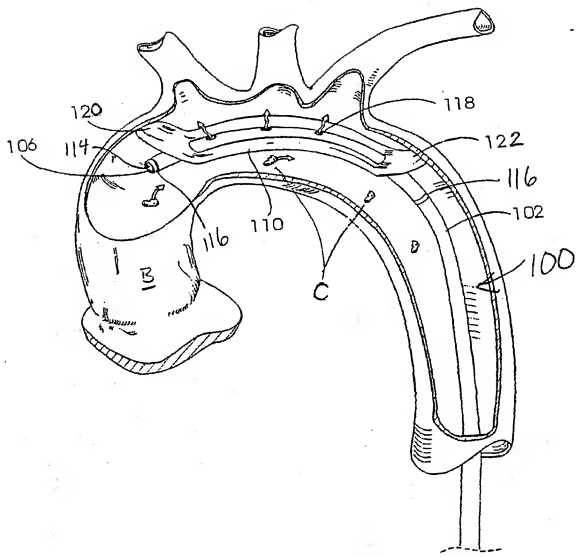


FIG 1

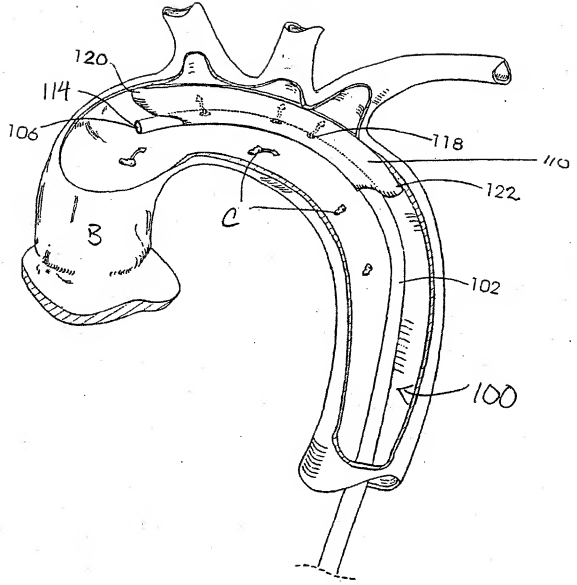
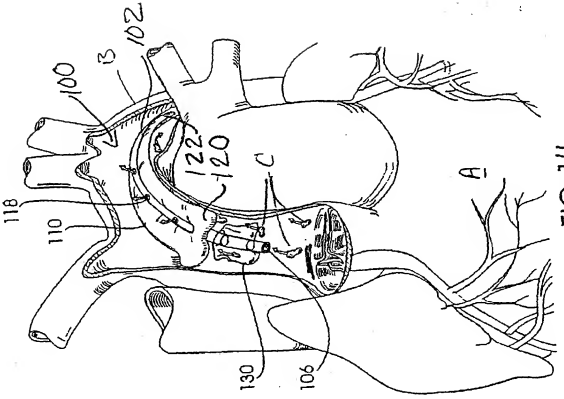


FIG 12


102
B
100
122
120
C
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118
110
130
106

FIG 14

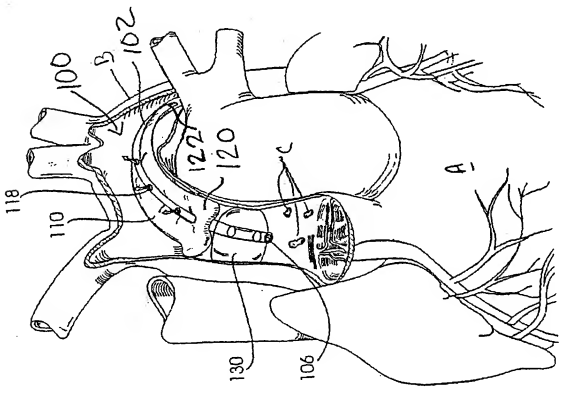
100
B
102
122
120
C
A
118
110
130
106

FIG 13

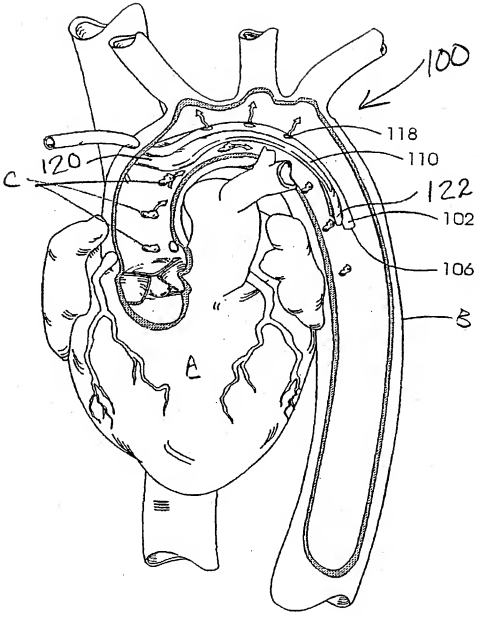

FIG 15

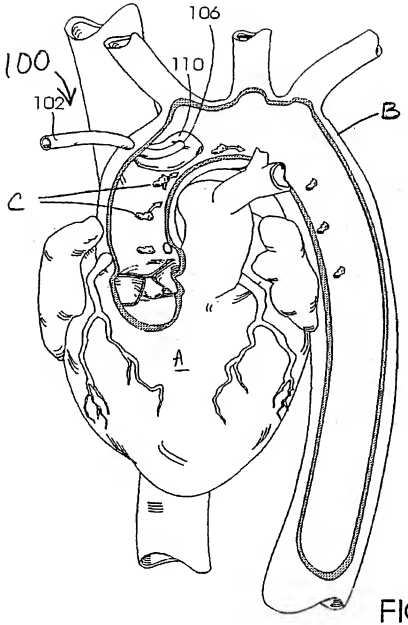

FIG 16

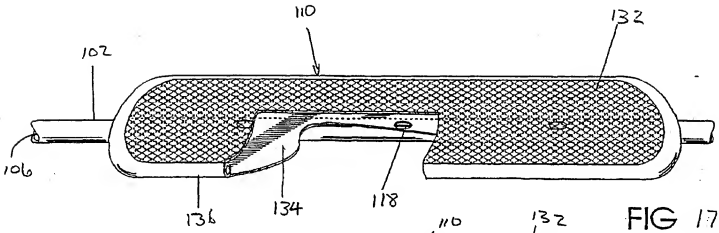

FIG 17

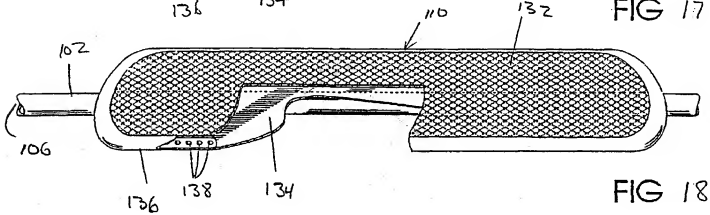

FIG 18

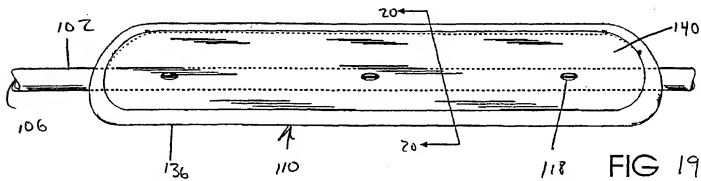

FIG 19

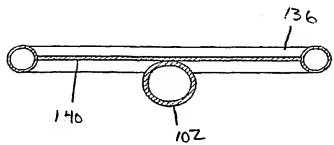

FIG 20

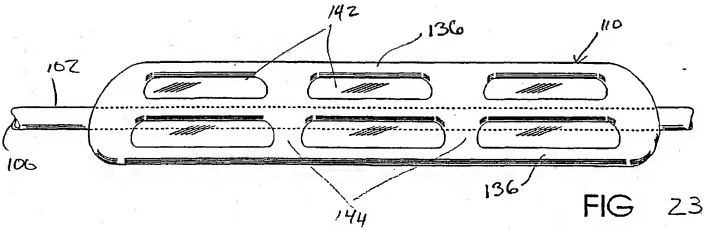

FIG 23

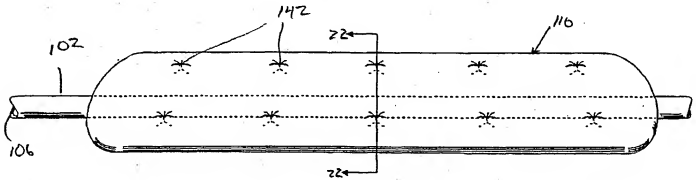

FIG 21

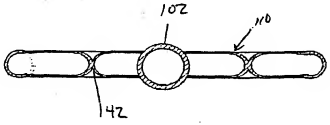

FIG 22

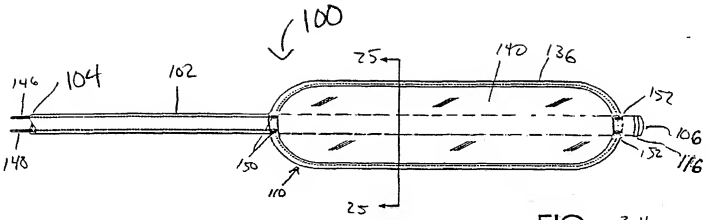

FIG 24

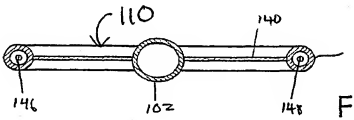

FIG 25

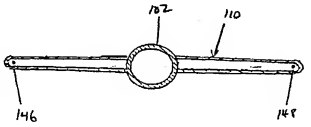

FIG 26

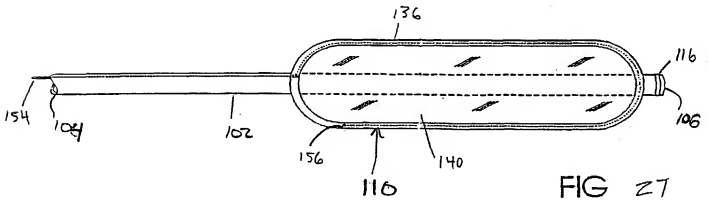

FIG 27

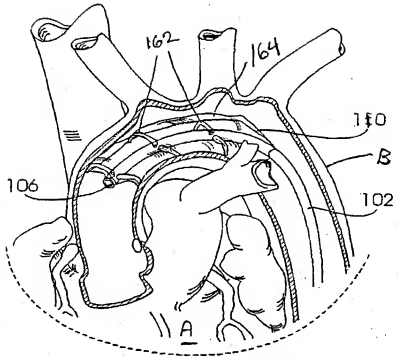

FIG 28

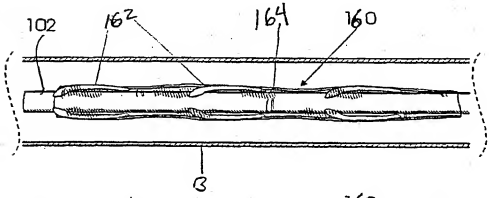

FIG 29

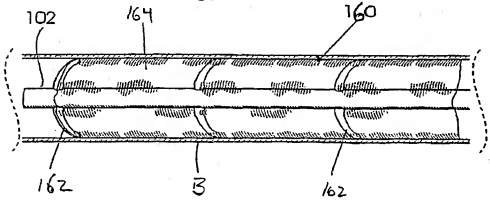

FIG 30

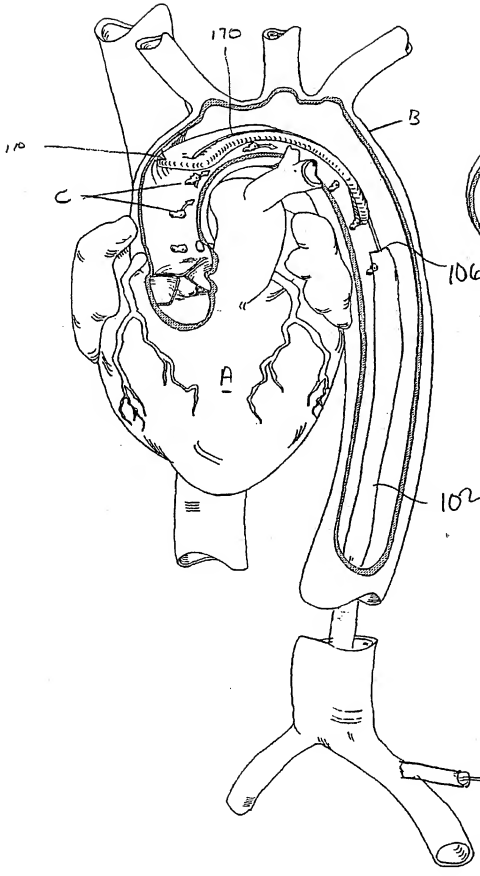

FIG 31

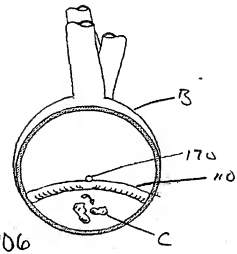

FIG 32

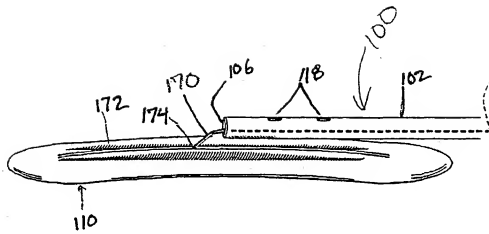

FIG 34

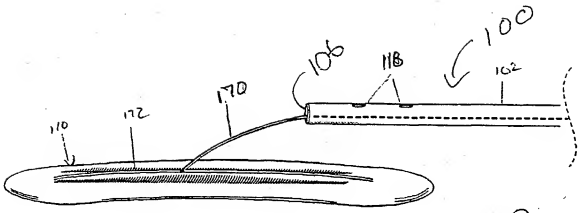

FIG 33

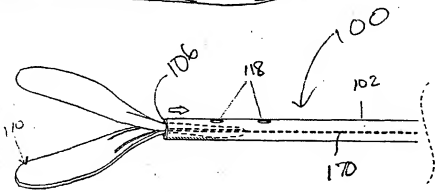

FIG 35

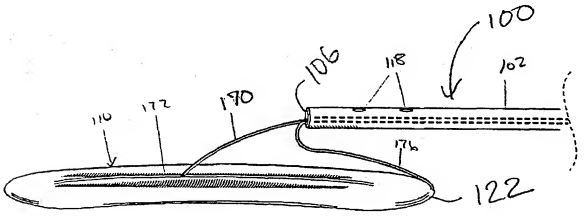

FIG 36

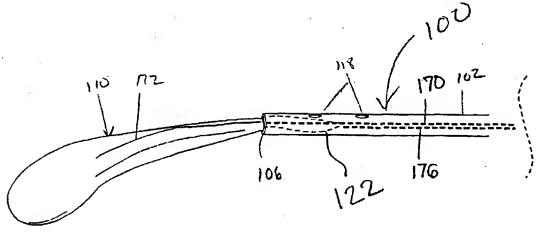

FIG 37

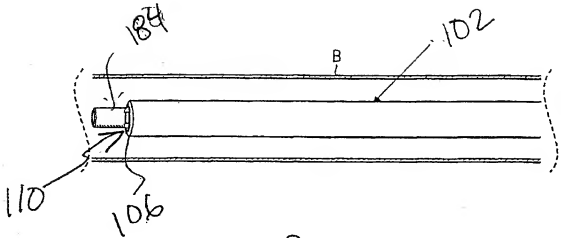

FIG 39

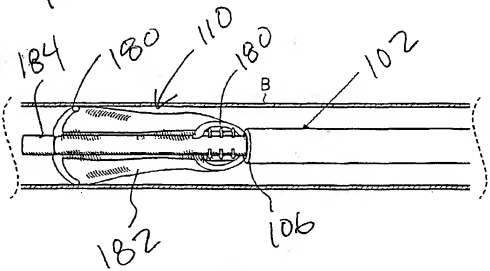

FIG 40

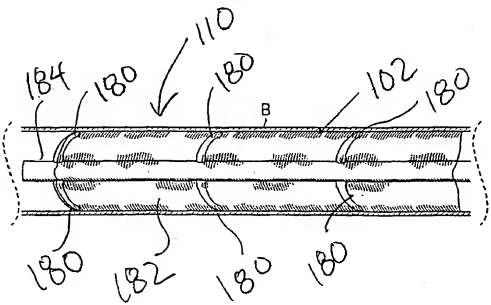

FIG 38

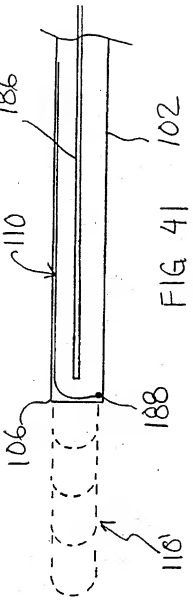

FIG 41

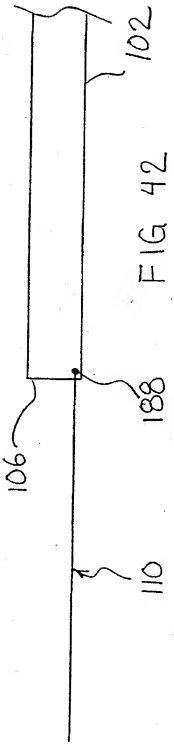

FIG 42

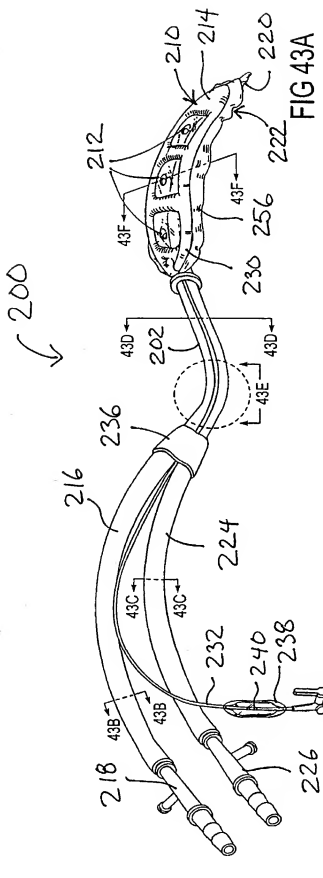

FIG 43A

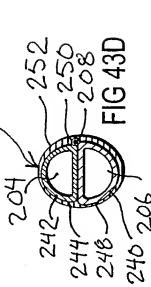

FIG 43D

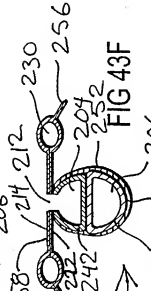

FIG 43F

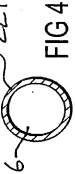

FIG 43C

FIG 43B

FIG43E

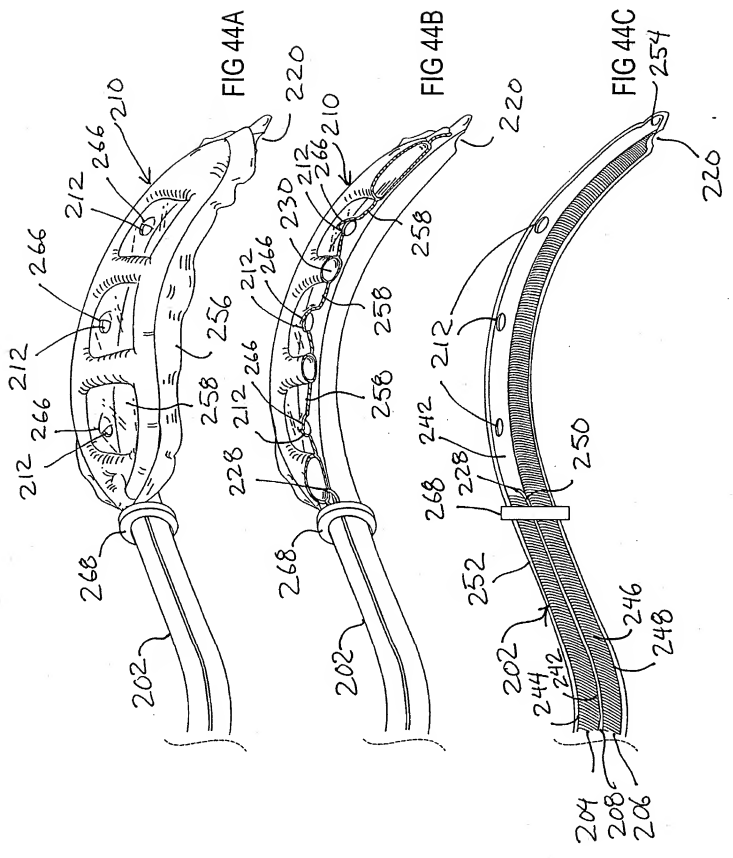
FIG 44A
FIG 44B
FIG 44C
210
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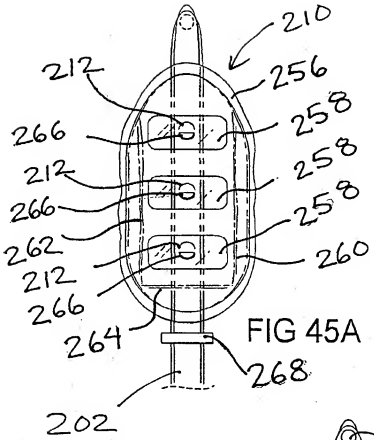


FIG 45A

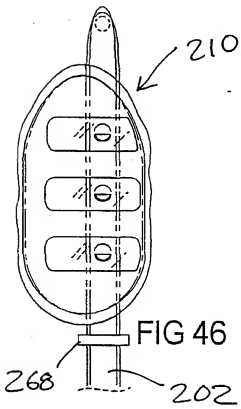


FIG 46

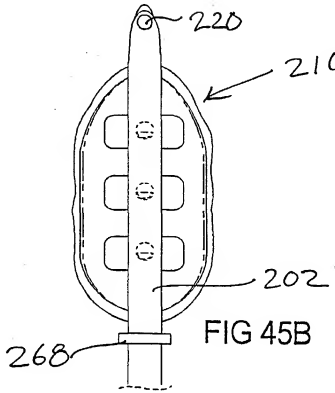


FIG 45B

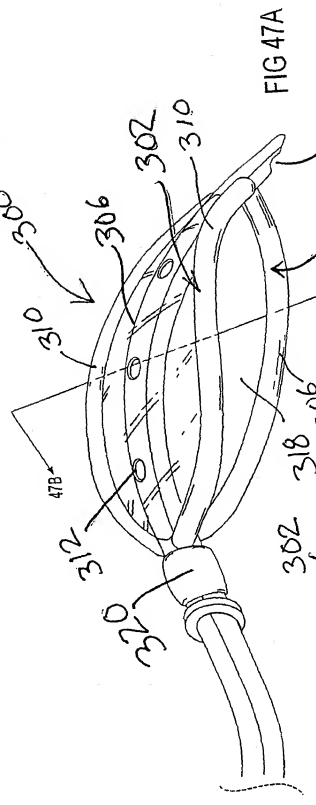


FIG 47A

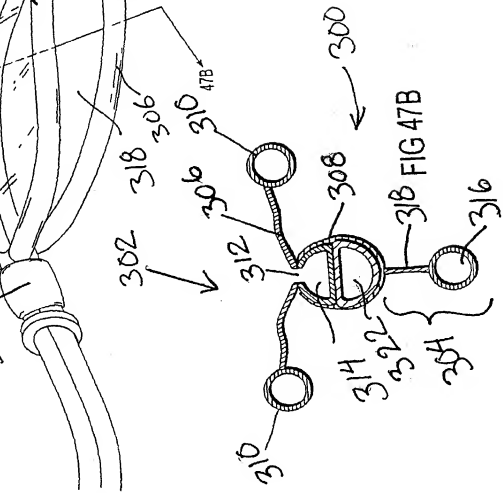


FIG 47B

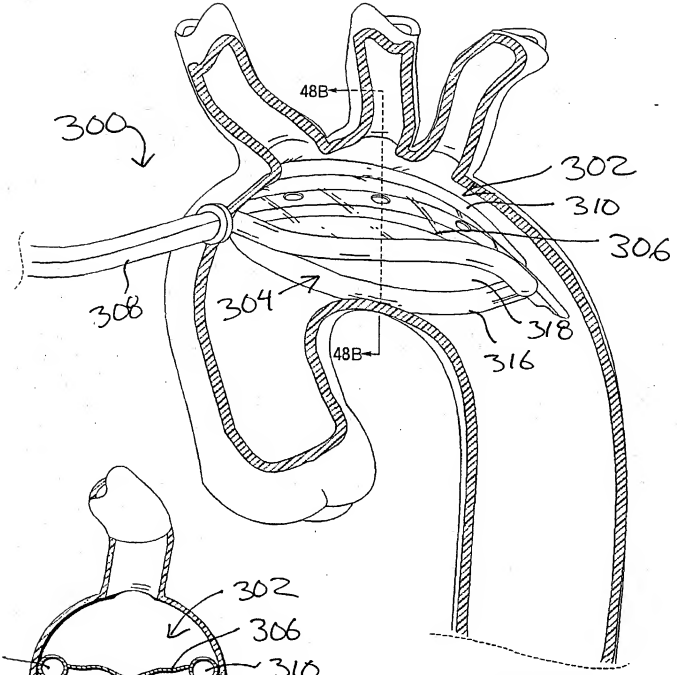


FIG 48A

FIG 48B

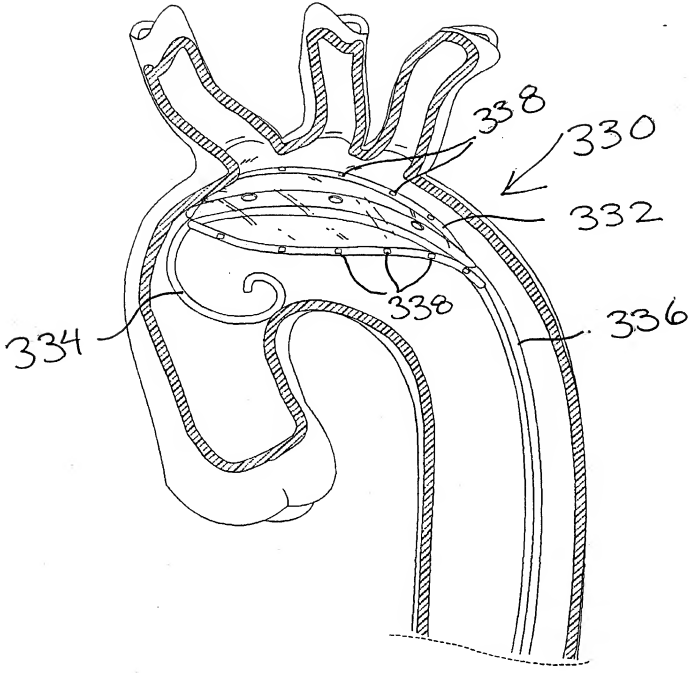


FIG 49

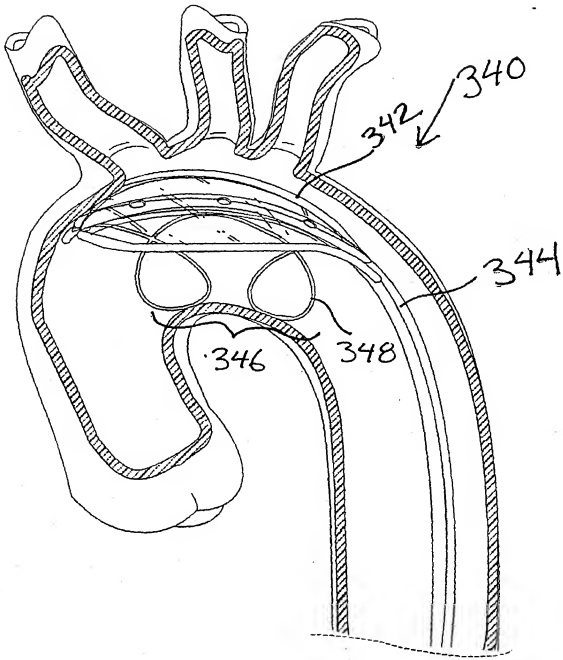


FIG 50

FIG 51

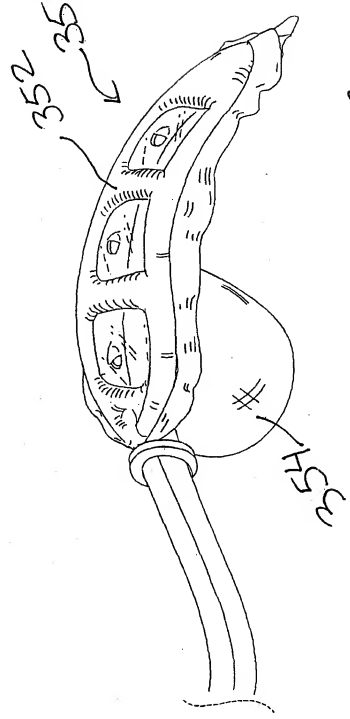
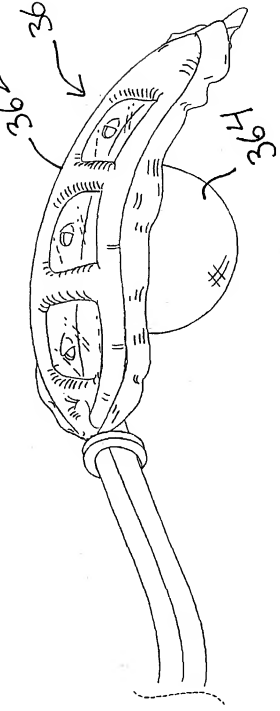


FIG 52



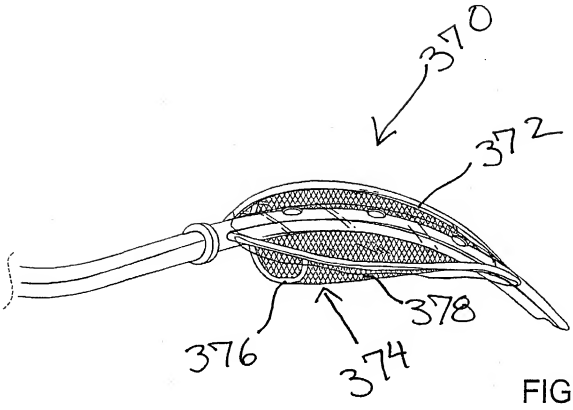


FIG 53

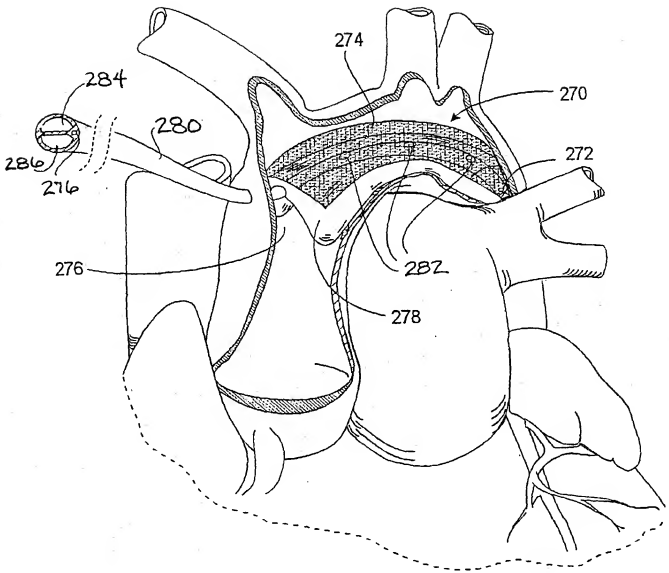


FIG 54

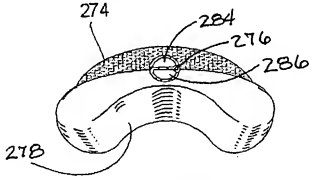


FIG 55

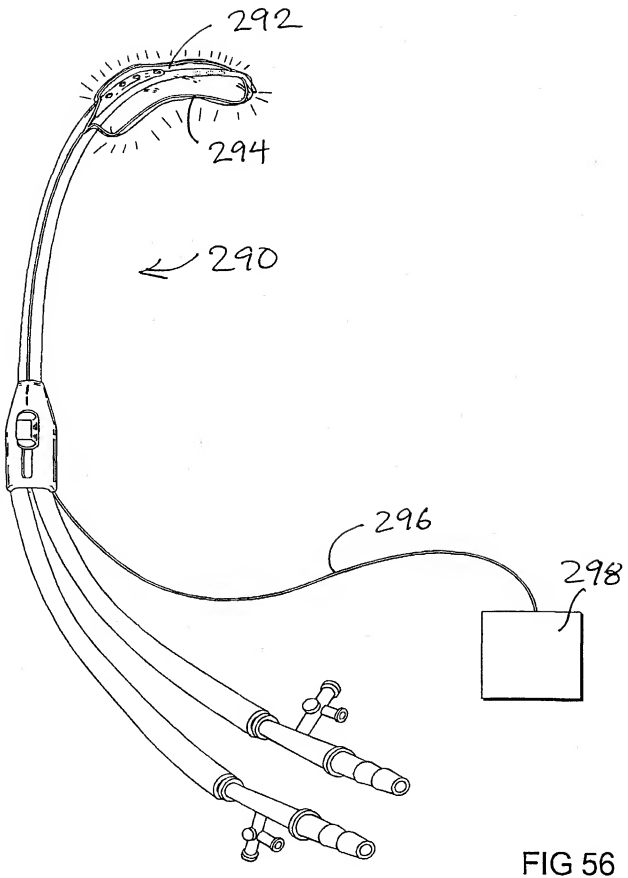


FIG 56

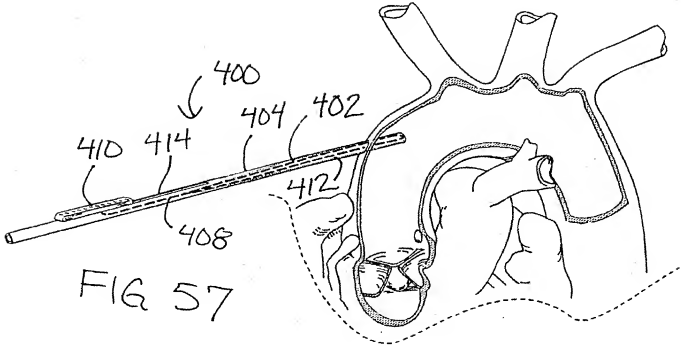


FIG 57

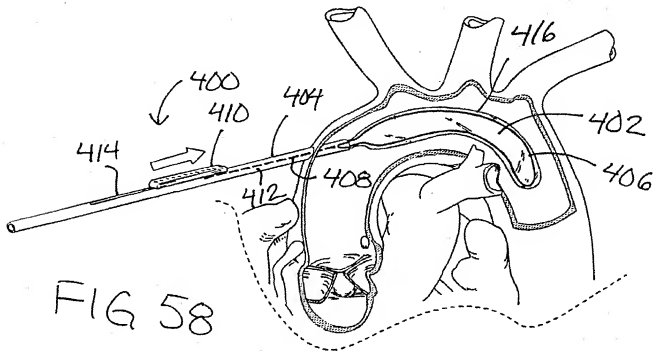


FIG 58

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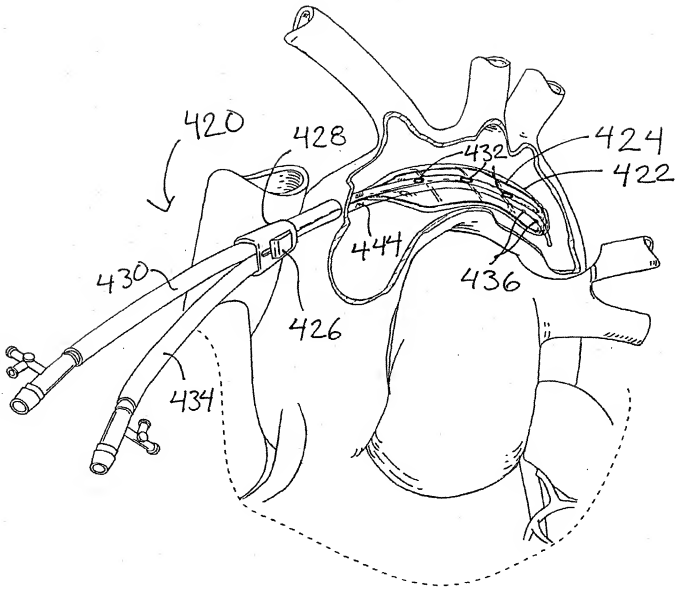

FIG 59

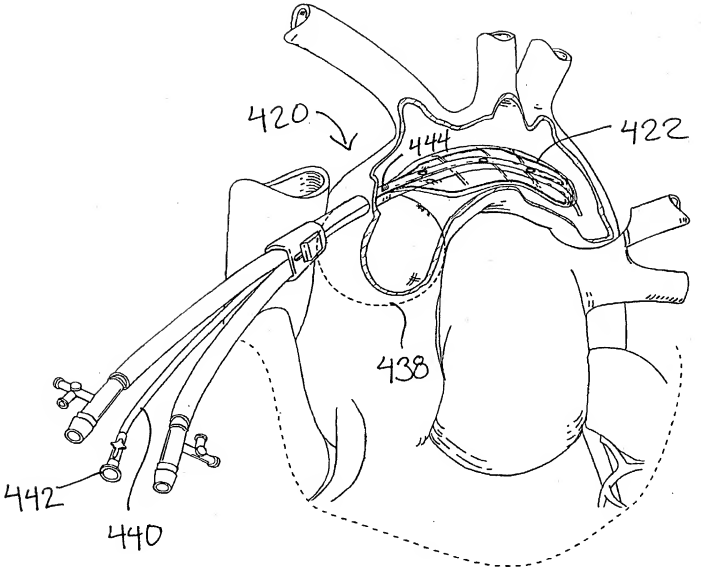

FIG 60

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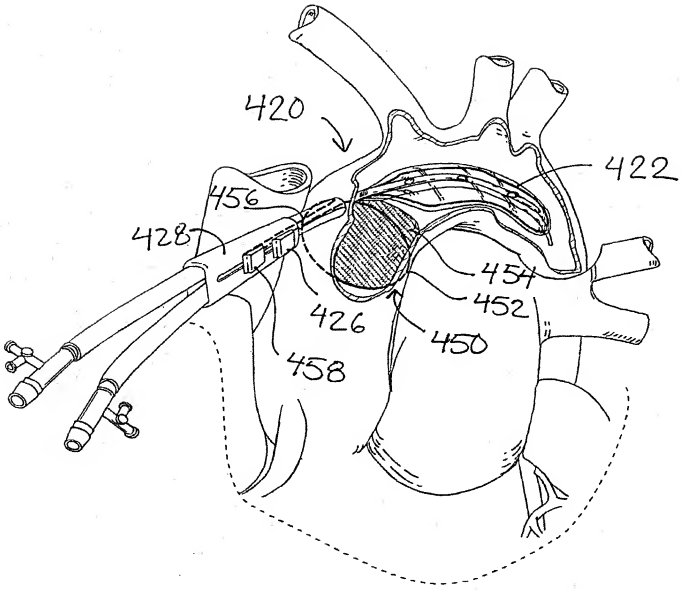

FIG 61

Practitioner's Docket No. ARDE.59410 PATENT #5.

COMBINED DECLARATION AND POWER OF ATTORNEY
NATIONAL STAGE OF PCT APPLICATION

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is for a national stage of a PCT application.

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am an original, first and joint inventor of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

AORTIC CATHETER WITH FLOW DIVIDER AND METHODS
FOR PREVENTING CEREBRAL EMBOLIZATION

SPECIFICATION IDENTIFICATION

The specification was described and claimed in PCT International application no. PCT/US00/01485, filed on January 22, 2000.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in 37 Code of Federal Regulations, Section 1.56.

PRIORITY CLAIM (35 U.S.C. §§ 119(a)-(d), (f), 172, and 365(a) and (b))

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

Such applications have been filed as follows.

PRIOR PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §§ 119(a)-(d)

INDICATE IF PCT	APPLICATION NUMBER	DATE OF FILING	PRIORITY CLAIMED UNDER 35 U.S.C. §119
PCT	PCT/US00/01485	January 22, 2000	no

Practitioner's Docket No. ARDE.59410 *PATENT*

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

APPOINTED PRACTITIONER(S)	REGISTRATION NUMBER(S)
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Michael S. Doll	44,092
Craig McLaughlin	44,925
Michael J. Moffat	39,304
James J. Leary	35,237

I hereby appoint the practitioner(s) associated with the Customer Number 27629 to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Practitioner's Docket No. RDE.59410 *PATENT*

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